

Sent: 28 Jun 2018 10:56:49 +0000
To: Jilani, Shahla (HHS/IOS); Policy Briefings Scheduler (OS/IOS); Stannard, Paula (HHS/IOS); Lapinski, Mary-Sumpter (HHS/IOS); Wynne, Maggie (HHS/IOS); Brooks, John (HHS/IOS); Bell, Kathryn (HHS/IOS); Caliguiri, Laura (HHS/IOS); Agnew, Ann (HHS/IOS); Malliou, Ekaterini (OS/IOS); Gabriel, Edward (OS/ASPR/IO); Meekins, Chris (OS/ASPR/IO); Flick, Heather (OS/OGC); Moughalian, Jen (HHS/ASFR); Cochran, Norris (HHS/ASFR); Abram, Anna (FDA/OC); Kalavritinos, Jack (FDA/OC); Ford-Barnes, Arwenthia (HHS/ASPR/IO); Kadlec, Robert (OS/ASPR/IO); Palmer, Ashley (OS/ASFR); Andrews, Sean (OS/ASPR/IO); Alton, Jennifer (OS/ASPR/IO) (CTR); Yeskey, Kevin (OS/ASPR/IO) (CTR); Horska, Katerina (HHS/IOS); Thompson, Donna (OS/ASPR/IO) (CTR); Street, Amanda (HHS/IOS); Stevenson, Sarah-Lloyd (HHS/IOS); Fantinato, Jessica (OS/ASPR/OEM)
Cc: Robinson, Wilma (HHS/IOS); Hawkins, Jamar (HHS/OS); Bowles, Jamil (HHS/IOS); Stimson, Brian (HHS/OGC); Bowman, Matthew (HHS/OGC); Stephan, Briana (OS/ASPR/IO); Pence, Laura (HHS/IOS); Kemper, Laura (HHS/ASL)
Subject: ASPR Briefing for Policy Team - [AGENDA ATTACHED]
Attachments: Agenda_ASPR Brief to OS Policy Team 1_24_2018.docx



Purpose: Continuation meeting with Counselors. Please contact Dr. Ekaterini Malliou should you have any questions.

Meeting Participants:

Counselors: Paula Stannard, Mary-Sumpter Lapinski, Maggie Wynne, John Brooks, Kathryn Bell

Deputy Secretary's Office: Laura Caliguiri

Exec Sec: Ann Agnew, Ekaterini (Kat) Malliou, Katerina Horska

ASPR: Edward Gabriel, Chris Meekins, Robert Kadlec, Sean Andrews; Jennifer Alton, Kevin Yeskey

OGC: Heather Flick

ASFR: Jen Moughalian, Norris Cochran

FDA: Anna Abram - via phone; Jack Kalavritinos - via phone

Location: Exec Sec Conf Rm 614H; (b)(6) Passcode (b)(6) Leader Code (b)(6)

Contact: Dr. Katerina Horska at Katerina.Horska@hhs.gov or 202-690-6819

ASPR Brief to HHS/OS Policy Team

Agenda

January 24, 2018

I. Welcome and Introductions

II.

(b)(5)

III.

IV.

V. Additional Items for Discussion

Sent: 28 Jun 2018 10:56:49 +0000
To: Malliou, Ekaterini (OS/IOS); Policy Briefings Scheduler (OS/IOS); Stannard, Paula (HHS/IOS); Lapinski, Mary-Sumpter (HHS/IOS); Wynne, Maggie (HHS/IOS); Brooks, John (HHS/IOS); Bell, Kathryn (HHS/IOS); Caliguiri, Laura (HHS/IOS); Agnew, Ann (HHS/IOS); Gabriel, Edward (OS/ASPR/IO); Meekins, Chris (OS/ASPR/IO); Flick, Heather (OS/OGC); Moughalian, Jen (HHS/ASFR); Cochran, Norris (HHS/ASFR); Abram, Anna (FDA/OC); Kalavritinos, Jack (FDA/OC); Ford-Barnes, Arwenithia (HHS/ASPR/IO); Kadlec, Robert (OS/ASPR/IO); Palmer, Ashley (OS/ASFR); Andrews, Sean (OS/ASPR/IO); Alton, Jennifer (OS/ASPR/IO) (CTR); Yeskey, Kevin (OS/ASPR/IO) (CTR); Horska, Katerina (HHS/IOS); Thompson, Donna (OS/ASPR/IO) (CTR); Street, Amanda (HHS/IOS); Stevenson, Sarah-Lloyd (HHS/IOS)
Cc: Robinson, Wilma (HHS/IOS); Hawkins, Jamar (HHS/OS); Bowles, Jamil (HHS/IOS); Stimson, Brian (HHS/OGC); Bowman, Matthew (HHS/OGC); Stephan, Briana (OS/ASPR/IO); Pence, Laura (HHS/IOS); Kemper, Laura (HHS/ASL)
Subject: [UPDATE] ASPR Briefing for Policy Team - [MATERIALS ATTACHED]
Attachments: GHSI Invite - USA.PDF, GHSI One-pager_30Jan2018.docx, Agenda_ASPR Brief to OS Policy Team 1_31_2018.docx



Purpose: Continuation meeting with Counselors.

Meeting Participants:

Counselors: Paula Stannard, Mary-Sumpter Lapinski, Maggie Wynne, John Brooks, Kathryn Bell

Deputy Secretary's Office: Laura Caliguiri

Exec Sec: Ann Agnew, Katerina Horska

ASPR: Edward Gabriel, Chris Meekins, Robert Kadlec, Sean Andrews; Jennifer Alton, Kevin Yeskey

OGC: Heather Flick

ASFR: Jen Moughalian, Norris Cochran

FDA: Anna Abram - via phone; Jack Kalavritinos - via phone

Location: Deputy Secretary's Conference Room 607G; (b)(6) Passcode (b)(6) Leader Code (b)(6)

Contact: Katerina Horska at Katerina.Horska@hhs.gov or 202-690-6819



Department
of Health

*From the Rt Hon Jeremy Hunt MP
Secretary of State for Health and Social Care*

39 Victoria Street
London
SW1H 0EU

020 7210 4850

Hon. Eric D. Hargan
Acting Secretary of Health and Human Services
200 Independence Avenue, SW
Washington DC, 20201
United States

24 JAN 2018

Dear Hon. Hargan,

**MINISTERIAL MEETING OF THE GLOBAL HEALTH SECURITY
INITIATIVE.**

On behalf of the Government of the United Kingdom of Great Britain and Northern Ireland I have pleasure in formally inviting you to join me in London for the 18th annual Ministerial Meeting of the Global Health Security Initiative (GHSI).

The GHSI brings together the Ministers, Secretaries and Commissioners from Canada, the United States, Mexico, the United Kingdom, France, Germany, Italy, Japan, and the European Commission to strengthen global preparedness and response to threats of chemical, biological, and radio-nuclear terrorism, as well as pandemic influenza. It has also been instrumental in combatting bio-security threats such as Zika and Ebola. The World Health Organization (WHO) serves as an expert advisor to the GHSI.

2018 marks the centenary of the outbreak of Spanish Flu pandemic, which killed between 50 and 100 million people. Our meeting will include a focus on the threat and challenges that a global influenza pandemic would present today. It will allow us to reflect on our collective strategies to respond to a future pandemic as well as to discuss effective communication approaches before and during a crisis when we are confronted with uncertain information in a constantly changing situation.

The meeting will take place on Friday 9 March 2018 at the Crick Institute and will be preceded by a formal welcome dinner on the evening of Thursday 8 March at the Royal College of Physicians.

My officials will be in contact with all the practical information you and your delegation will need to be aware of in order to attend the event.

I do hope you can join us for both the meeting and the welcome dinner. I am very much looking forward to welcoming you and your colleagues to London.

Yours sincerely
Jeremy

JEREMY HUNT

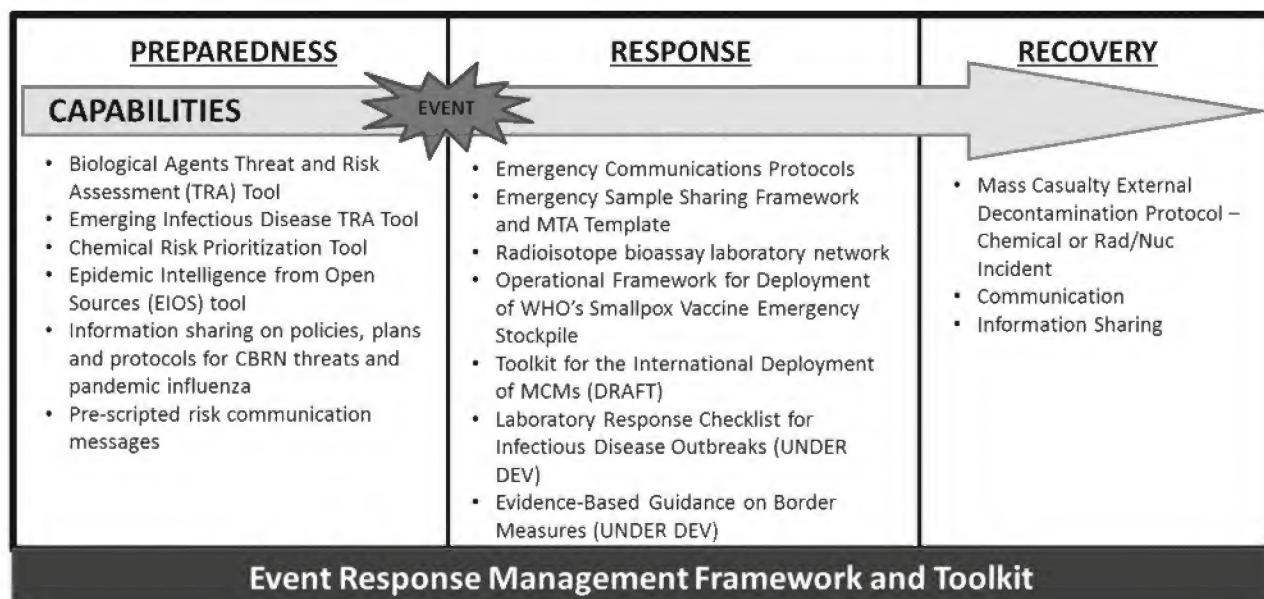
Background: Global Health Security Initiative

Mandate and Membership

The Global Health Security Initiative (GHSI) is an informal network of countries that came together shortly after the September 11, 2001 attacks to **ensure exchange and coordination of practices within the health sector in confronting new threats and risks to global health posed by terrorism and emerging infectious diseases**. Members of the GHSI are Canada, the European Commission, France, Germany, Italy, Japan, Mexico, the United Kingdom, and the United States; the World Health Organization (WHO) serves as a technical advisor.

The mandate of the GHSI is to undertake concerted global action to **strengthen public health preparedness and response to the threat of international chemical, biological, radiological, and nuclear terrorism and pandemic influenza**. Over the years, **the network has leveraged its threat-specific work to improve all-hazards preparedness and has regularly supported** response, coordination, and information exchange during non-intentional events, including the H1N1 influenza pandemic, the Fukushima nuclear disaster, Middle East Respiratory Syndrome (MERS), Ebola, and Zika.

Preparedness and Response Tools



Upcoming Events

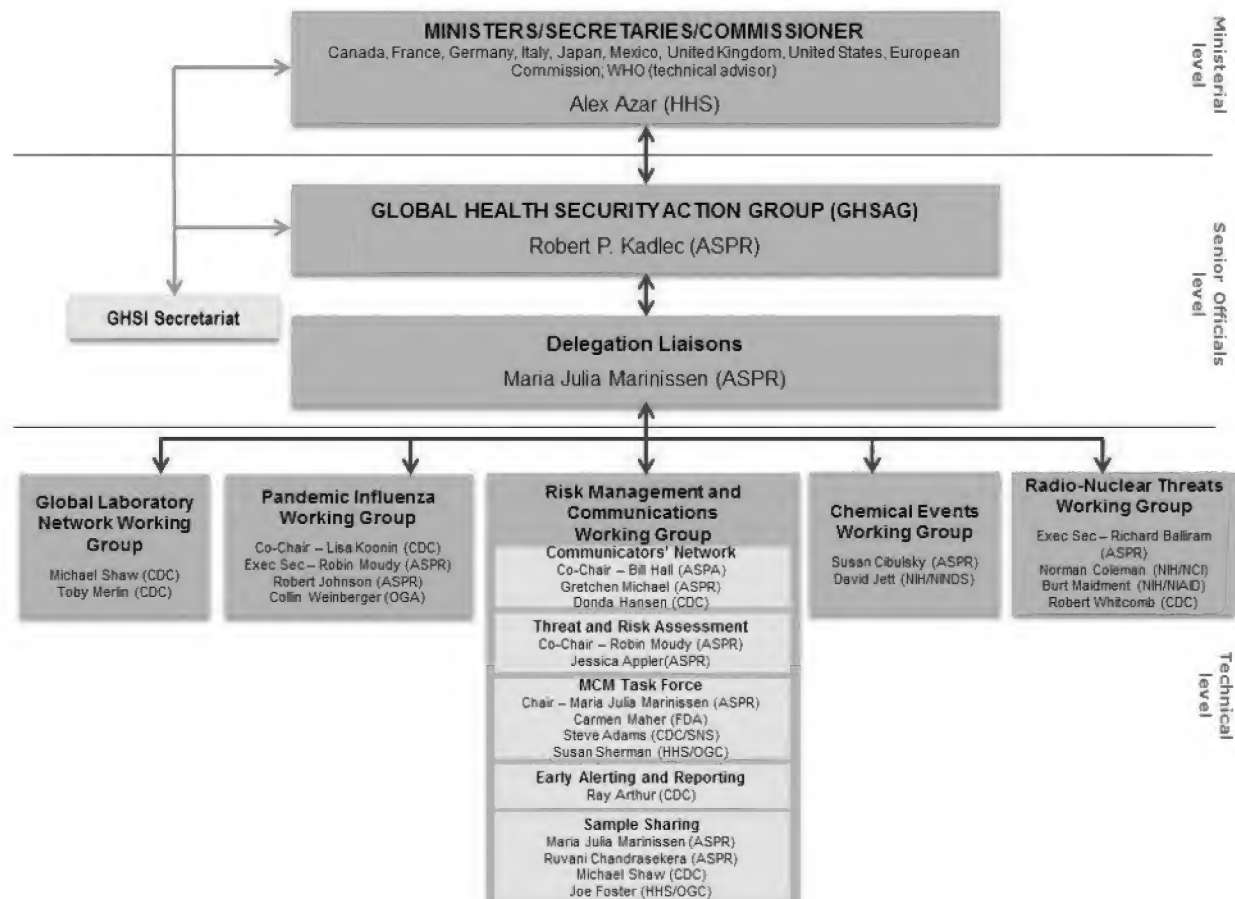
March 8-9, 2018:	Senior Officials and Ministerial meetings (London, UK)
April 2018:	GHSI Event Management Response Framework Exercise (London, UK)
TBD	GHSI Chem Events Working Group Meeting (Boston, MA)
June 2018:	Senior Officials meeting (Ottawa, Canada)

Structure of GHSI

Ministerial Meetings: The annual meeting of Health Ministers fosters dialogue on topical policy issues and sets priorities for the upcoming year.

Global Health Security Action Group (GHSAG): The GHSAG was established by Ministers to develop and implement concrete actions to improve global health security. It also serves as a network of rapid communication/reaction in the event of a crisis. The Assistant Secretary for Preparedness and Response is the U.S. Senior Official for the GHSAG. GHSAG members exchange information regarding global health security issues, discuss policy priorities for the network, review progress on technical-level activities, and assist in the preparation of Ministerial meetings.

Technical/Scientific Level: Technical experts, including representatives from across HHS, meet throughout the year to coordinate and collaborate on various topics affecting global health security.



ASPR Brief to HHS/OS Policy Team

Agenda

January 31, 2018

I. Welcome and Introductions

II.

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III.

IV.

V. Additional Items for Discussion

From: Stannard, Paula (HHS/IOS)
Sent: 27 Jun 2017 13:25:56 +0000
To: Stannard, Paula (HHS/IOS)
Subject: ASPR
Attachments: ASPR - Final Memo with ps edits.docx, ASPR - Final Framework.docx, ASPR - Final Review Group.docx

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of the Freedom of Information Act

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of the Freedom of Information Act

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of the Freedom of Information Act

From: Office of the Executive Secretary Master Calendar (HHS/OS)
Sent: 7 Jun 2017 22:27:29 +0000
To: Office of the Executive Secretary Master Calendar (HHS/OS);Skrzycki, Kristin (HHS/IOS);Gartland, Molly (HHS/IOS);Stannard, Paula (HHS/IOS);Lenihan, Keagan (HHS/IOS);Brooks, John (HHS/IOS);Lapinski, Mary-Sumpter (HHS/IOS);Wynne, Maggie (HHS/IOS);Schaefer, Nina (HHS/IOS);Street, Amanda (HHS/IOS);Stevenson, Sarah-Lloyd (HHS/IOS);Bell, Kathryn (HHS/IOS);Caligui, Laura (HHS/IOS);Greenstein, Bruce (OS/IOS);Agnew, Ann (HHS/IOS);Cotter, Janice (HHS/IOS);Pelekoudas, Kristina (HHS/IOS);Malliou, Ekaterini (OS/IOS);Stirrup, Heidi (HHS/IOS);Mansdoerfer, David (HHS/IOS);Bird, Catherine (HHS/IOS);Conrad, Patricia (HHS/IOS);Martinez, Cecilia (OS/IOS);Harrison, Jessica (OS/IOS);Lagomarsino, Katie (OS/IOS);Cordova, Jon (OS/ASA);Moughalian, Jen (HHS/ASFR);Arbes, Sarah (HHS/ASL);Aramanda, Alec (OS/ASL);Palmer, Ashley (HHS/ASL);Lawrence, Courtney (HHS/ASL);Morse, Sara (HHS/ASL);Hayes, Sean (HHS/ASL);Lloyd, Matt (OS/ASPA);Murphy, Ryan (OS/ASPA);Marre, Alleigh (OS/ASPA);O'Brien, John (HHS/ASPE);Trueman, Laura (HHS/IEA);Manning, Teresa (HHS/OASH);Bell, March (HHS/OCR);Flick, Heather (OS/OGC);Bowman, Matthew (HHS/OGC);Cleary, Kelly (HHS/OGC);Alexander, Thomas (OS/OGA);Lucas, Jane (HHS/IOS);Morris, Genevieve (OS/ONC/IO);Fleming, John (OS/ONC);Pilato, Anna (ACF);Tignor, Beth (HHS/IOS);Balenger, Juanita (HHS/IOS);Kouzoukas, Demetrios (CMS/OA);Pate, Randy (CMS/CCIIO);Abram, Anna (FDA/OC);Kalavritinos, Jack (FDA/OC);Korch, George (OS/ASPR/IO);Gabriel, Edward (OS/ASPR/IO);Bright, Rick (OS/ASPR/BARDA);Phillips, Sally (HHS/ASPR/OPP);Scarborough, Jess (OS/ASPR/AMCG);Petillo, Jay (OS/ASPR/OFPA);Michael, Gretchen (OS/ASPR/COO);Fantinato, Jessica (OS/ASPR/OEM);Boyce, Don (OS/ASPR/OEM);Stephan, Briana (OS/ASPR/IO);Weinberger, Collin (OS/ASPR/IO) (CTR)
Cc: Hawkins, Jamar (HHS/OS)
Subject: Briefing for HHS Political Staff: ASPR 101 & Continuity of Operations Plan (COOP) ** MATERIALS, ATTACHED**
Attachments: Briefing Paper - ASPR 101.pptx, Briefing Paper - COOP.pptx

Briefing for HHS Political Staff

Event Name: ASPR 101 and COOP Briefing

Location: Thomas P. O'Neill Jr. Federal Building, Willow Room on Lower Level, 200 C St SW, Washington, DC 20024 (behind the Humphrey Building)

Date & Time: Tuesday, June 13, 2017, 3-4pm

Topic: ASPR 101 & Continuity of Operations Plan (COOP)

Briefing Materials: Attached



Reason: ASPR will brief the Secretary's policy team and deputy-level political staff on the role of the Office of the Assistant Secretary for Preparedness and Response (ASPR) and the Department's Continuity of Operations Plan (COOP).

Note: Please note that the Secretary, Chief of Staff, and the heads of HHS agencies have already been briefed or will be briefed and do not need to attend.

Introduction: The Office of the Assistant Secretary for Preparedness and Response (ASPR)

ASPR focuses on preparedness planning and response; building federal emergency medical operational capabilities; countermeasures research, advance development, and procurement; and grants to strengthen the capabilities of hospitals and health care systems in public health emergencies and medical disasters. The office provides federal support, including medical professionals through ASPR's National Disaster Medical System, to augment state and local capabilities during an emergency or disaster. The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies.

Introduction: ASPR Continuity of Operations (COOP)

The National Continuity Policy Implementation Plan (NCPIP) and the National Security Presidential Directive- 51/Homeland Security Presidential Directive- 20 (NSPD-51/HSPD-20), is an effort within individual executive departments and agencies to ensure that Primary Mission Essential Functions (PMEFs) continue to be performed during a wide range of emergencies, including localized acts of nature, accidents and technological or attack-related emergencies.

Briefing Agenda:

- 0 minutes:** ASPR 101 - Dr. George Korch, Ed Gabriel, Rick Bright, Sally Phillips, Jess Scarborough, Jay Petillo, Gretchen Michael
- 20 minutes:** COOP – Edward Gabriel, Jessica Fantinato, Don Boyce
- 20 minutes:** Questions & Answers

Lead: Dr. George Korch, Acting ASPR

Event POC: Dr. Ekaterini (Kat) Malliou, 202-286-4549, Ekaterini.Malliou@hhs.gov

Participants:

Office of the Chief of Staff	Kris Skrzycki, Molly Gartland
Office of Counselors	Paula Stannard, Keagan Lenihan, John Brooks, Mary-Sumpter Lapinski, Maggie Wynne, Nina Schaefer, Amanda Street, Sarah-Lloyd Stevenson, Kathryn Bell, Laura Caliguiri, Bruce Greenstein
Executive Secretariat	Ann Agnew, Executive Secretary Janice Cotter, Director

	Kristina Pelekoudas, Briefing Coordinator
White House Liaison	Heidi Stirrup, Deputy Director David Mansdoerfer, Director of Boards & Commissions Catherine Bird, Advisor
Scheduling and Advance Office	Patty Conrad, Director of Scheduling Cecilia Martinez, Director of Advance Jessica Harrison, Deputy Director Katie Lagomarsino, Trip Coordinator
ASA	Jon Cordova, Principal Deputy Assistant Secretary
ASFR	Jen Moughalian, Principal Deputy Assistant Secretary
ASL	Sarah Arbes, Principal Deputy Assistant Secretary Alec Aramanda, Deputy Assistant Secretary for Health Policy Ashley Palmer, Deputy Assistant Secretary for Health Care Reform Courtney Lawrence, Deputy Assistant Secretary for Human Services Laura Kemper-Holland, Deputy Assistant Secretary for Public Health and Science Sara Morse, Deputy Assistant Secretary for Congressional Liaison Sean Hayes, Director for Oversight and Investigations
ASPA	Matt Lloyd, Principal Deputy Assistant Secretary Ryan Murphy, Deputy Assistant Secretary Alleigh Marre, Chief Spokesperson
ASPE	John O'Brien, Deputy Assistant Secretary for Health Policy
IEA	Laura Trueman, Deputy Director
OASH	Teresa Manning, Deputy Assistant Secretary for Population Affairs
OCR	Thomas March Bell, Chief of Staff
OGC	Heather Flick, Deputy General Counsel Matt Bowman, Deputy General Counsel Kelly Cleary, Deputy General Counsel
OGA	Thomas Alexander, Principal Deputy Assistant Secretary
OHR	Jane Lucas, Deputy Director
ONC	Genevieve Morris, Principal Deputy National Coordinator John Fleming, Deputy Assistant Secretary
ACF	Anna Pilato, Deputy Assistant Secretary
ACL	Beth Tignor, Policy Advisor for the Commissioner of the Administration on Disabilities Juantita Balenger, Advisor

CMS	Demetrios Kouzoukas, Principal Deputy Admin and Director, Center for Medicare Randy Pate, Deputy Administrator and Director of CCIIO
FDA	<u>Anna Abram</u> , Deputy Commissioner for Policy, Planning, Legislation, and Analysis Jack Kalavritinos, Associate Commissioner for External Affairs

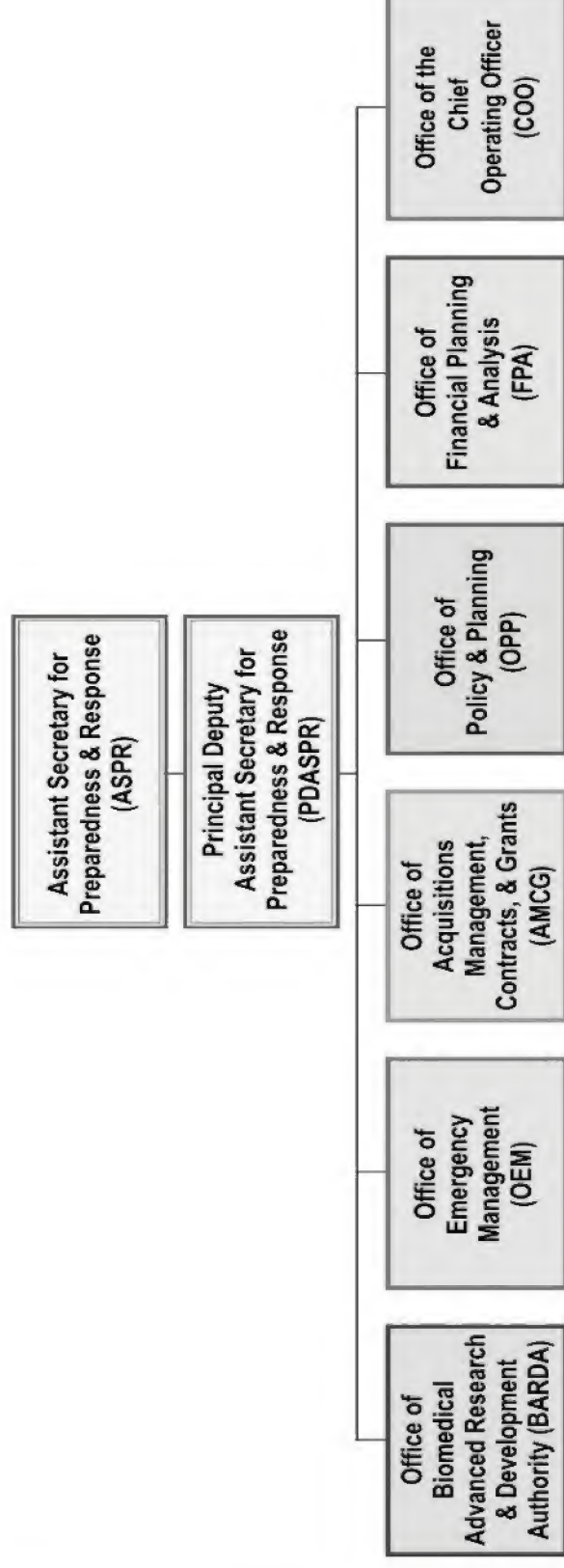


ASPR 101: Overview of ASPR Programs and Capabilities

U.S. Department of Health and Human
Services (HHS) Office of the Assistant
Secretary for Preparedness and Response
(ASPR) 06/13/2017



ASPR Organizational Chart



Resilient People. Healthy Communities. A Nation Prepared.

ASPR's Mission

“Lead the country in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters by supporting our communities’ ability to withstand adversity, strengthening our health and response systems, and enhancing national health security.”



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HHS ASPR Coordinates Federal Public Health and Medical Response

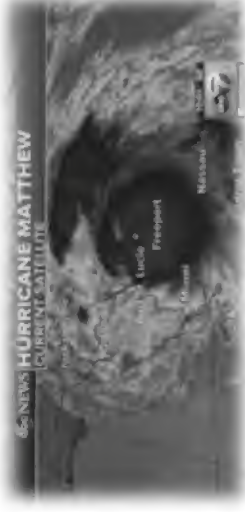
- Emergency Support Function (ESF)-8 is the mechanism for Federal assistance to supplement State, tribal, and local resources in response to a public health and medical disaster, potential or actualPublic health needsMedical care needsBehavior health needsVeterinary and/or animal health issues



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Operational Response to Events

Events come in “all shapes and sizes”; they are both, expected and unexpected.



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Office Of Emergency Management (OEM)

- Leads the response activities under NRF-ESF#8 Directs the Secretary's Operations Center (SOC) Trains and manages the Incident Response Coordination (IRC) Teams Manages Public Health & Medical recovery activities Coordinates and executes the HHS Continuity of Operations (COOP) and Continuity of Government (COG) programs Plans, implements and evaluates response exercises Manages hospital preparedness grants through National Hospital Preparedness Program (HPP) Manages National Disaster Medical System (NDMS)

Secretary's Operations Center (SOC)

- SOC = 24/7/365 Federal Operations Center
Operations Officers: Continuously monitor and analyze public health indicators and warnings, both domestically and internationally
GIS Support: Perform geospatial analysis and create visualization products
Information Technology Support: Provide IT support for all SOC information sharing and storage platforms
Command center for coordinated Federal ESF-8 response



NDMS Teams/Programs

- Teams: Disaster Medical Assistant Team (DMAT) Disaster Mortuary Response Team (DMORT) Disaster Mortuary Response Team – All Hazards (DMORT-AH) National Veterinary Response Team (NVRT) International Surgical Response Team (IMSURT)* Programs: Federal Patient Movement Mass Fatality Management Definitive Care (NDMS Hospitals)

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NDMS Teams in Action



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Other ASPR Emergency Response Capabilities

- Tactical Medicine Personnel Medical Shelter Support
Disaster Behavioral Health General Shelter Support
EOC Support
Vaccinations Mass Dispensing Hospital ACS/ Med Surge Mass Casualty Evacuation
Call Center Support
Epidemiology/ Surveillance Support



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OEM Regional Coordination Program

- Regional Emergency Coordinators (RECs) primarily focus on U.S. domestic preparedness and response efforts, connecting with state, local, tribal, territorial, and federal partners. Liaison Program staff connect ASPR with our DoD partners, International Organizations (WHO, PAHO) and with U.S. international and cross-border preparedness and response initiatives. RECs in each FEMA Region (several per region).

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HHS Response Assets Support Local/State Needs

- **US Public Health Service (USPHS) Commissioned Corps Rapid Deployment Force (RDF) Team Mental Health Team Medical Reserve Corps (MRC)** National network of local groups of volunteers supporting local health departments respond to community health needs



Medical Reserve Corps (MRC)

MRC units engage in their local communities to strengthen public health, improve emergency response capabilities, and build community resiliency. No MRC unit is the same — specific engagement activities vary by community need, volunteer skills and interest, and partner support.

Emergency Preparedness & Response



Public Health



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ASPR Fusion: Social Media Research



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Social Media Research Examples

- State of the Union
Aliso Canyon
Methane Leak
4th of July
Peace Officers Memorial
Flint Water Crisis
Nuclear Summit
Orlando/Pulse
Mass Shooting
Zika Virus
RNC/DNC
LA Flooding
Hurricane Matthew



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HHS emPOWER Initiative

Using Federal Health Data and Mapping to Advance
Emergency Preparedness, Response, Recovery and
Resilience



Data
Awareness
Preparedness
Resilience



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ASPR EMPOWER Initiative Mission

The mission is to provide readily meaningful, consumable and actionable data, maps, and tools to advance preparedness, inform and support response and recovery operations and decision-making, and to mitigate health system stress and adverse health outcomes in at-risk populations in every community.



T R A C I E

HEALTHCARE EMERGENCY PREPAREDNESS
INFORMATION GATEWAY

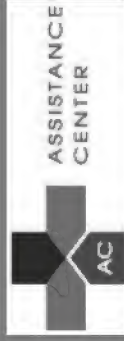
ASPR Technical Resources, Assistance Center, and Information Exchange

ASPR
ASSISTANT SECRETARY FOR
PREPAREDNESS AND RESPONSE

ASPR TRACIE: Three Domains



- Self-service collection of audience-tailored materials
- Subject-specific, SME-reviewed "Topic Collections"
- Unpublished and SME peer-reviewed materials highlighting real-life tools and experiences



- Personalized support and responses to requests for information and technical assistance
- Accessible by toll-free number (1844-5-TRACIE), email (askasprtracie@hhs.gov), or web form (ASPRtracie.hhs.gov)



- Area for password-protected discussion among vetted users in near real-time
- Ability to support chats and the peer-to-peer exchange of user-developed templates, plans, and other materials

ASPRtracie.hhs.gov

1-844-5-TRACIE

askasprtracie@hhs.gov

Biomedical Advanced Research & Development Authority (BARDA)

- The Biomedical Advanced Research and Development Authority (BARDA), within HHS ASPR, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies. BARDA Divisions: Division of Chemical, Biological, Radiological and Nuclear Medical Countermeasures, Influenza Division, Division of Regulatory & Quality Affairs, Strategic Science and Technology



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BARDA

- Was created by Congress to serve the critical needs of the USG for moving select products from basic research/early development through advanced development toward FDA licensure. Provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for biodefense and public health medical emergencies.

BARDA

Medical Countermeasures for All-Hazards



Medical Devices



Antimicrobials



Diagnostics

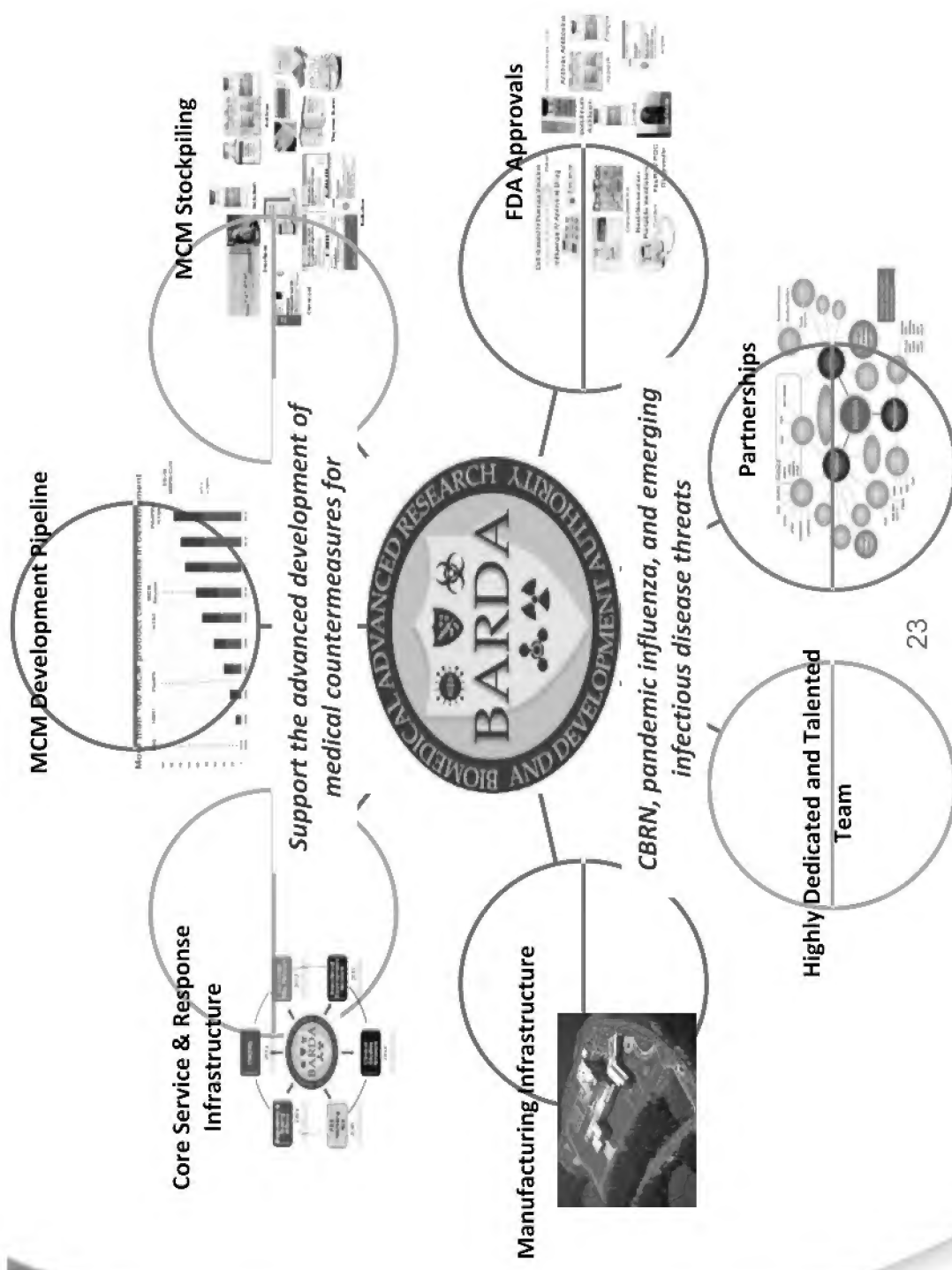


Vaccines

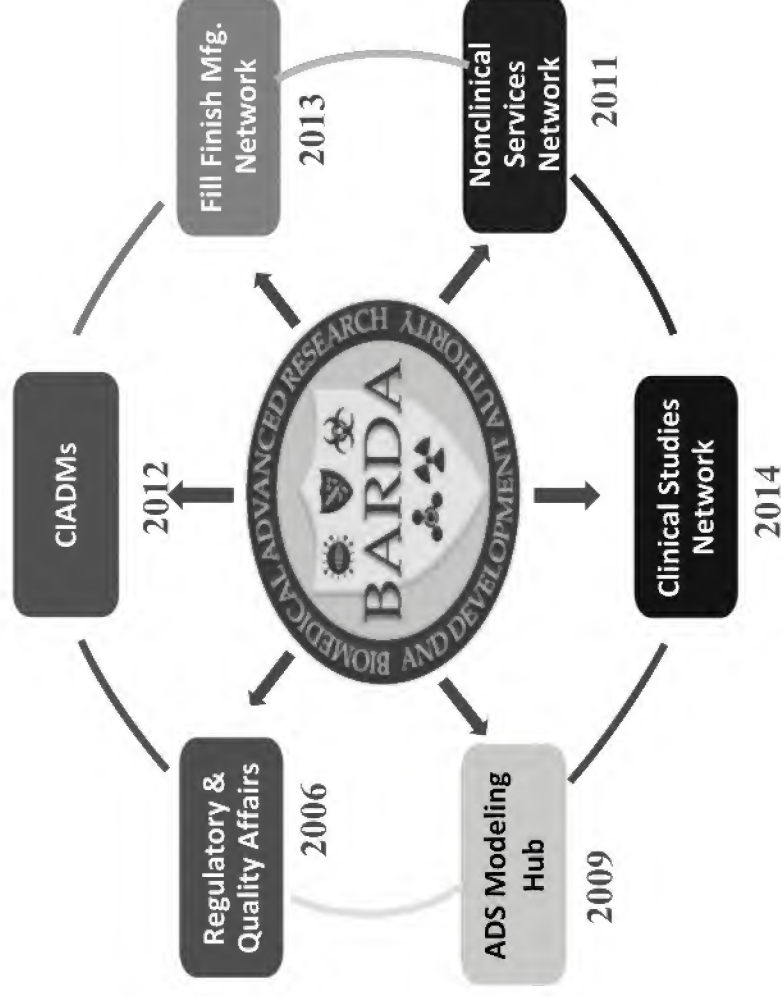


Therapeutics

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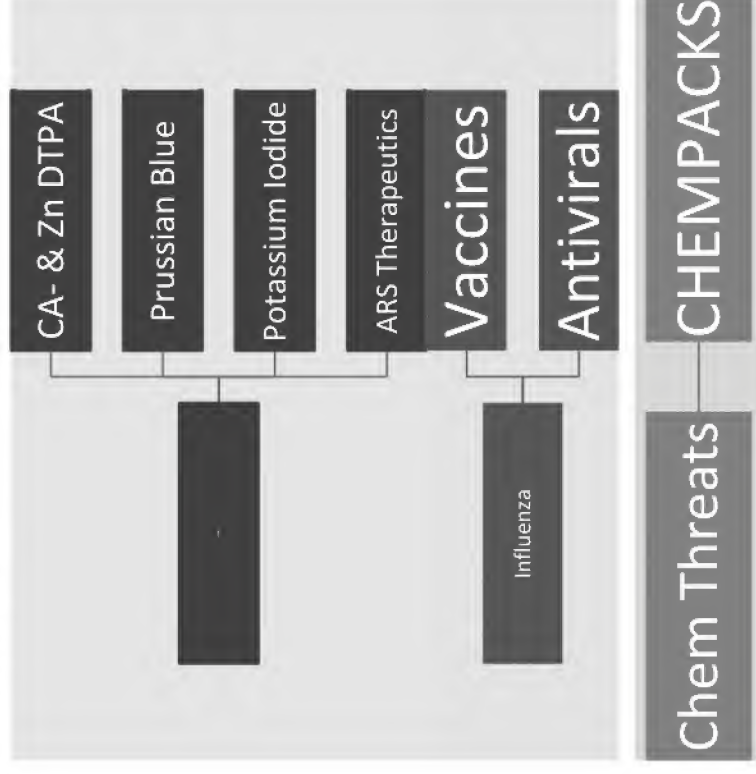
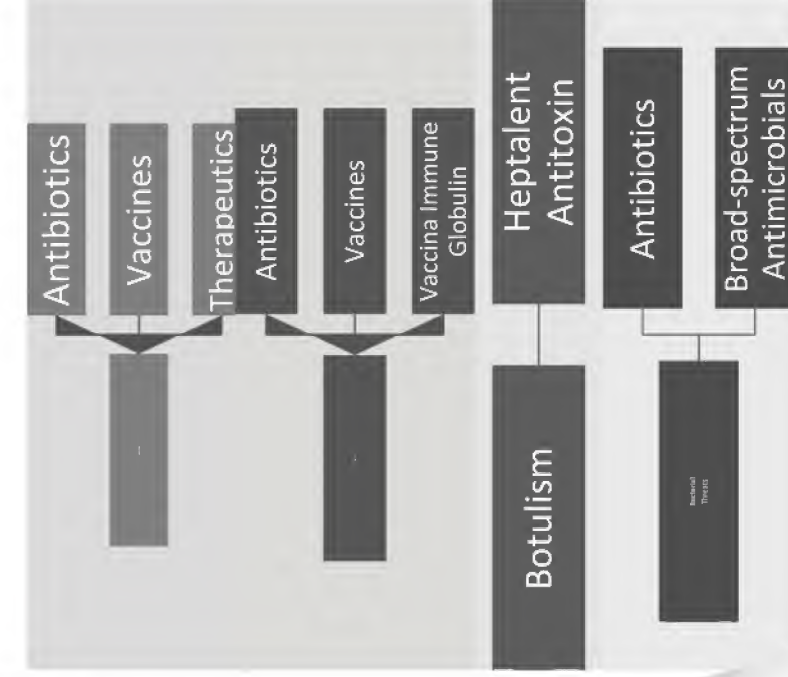


Emerging Threats Requires a Coordinated Response



CBRN and Flu Medical Countermeasures

A Toolkit for Public Health Preparedness



Innovative MCMs

- Product: "Recell" an autograft sparing technology dramatically reduces the amount of healthy skin that is required for skin grafting. A small piece of healthy skin can be removed and disaggregated to produce a cellular slurry that can be sprayed of the cleaned wound bed and promote wound healing.



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BARDA SNS MCM Development



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Office of Policy and Planning (OPP)

- *OPP Vision: Inspirational, Innovative and Influential Policy and Strategic Planning for Public Health Emergencies... A Nation Prepared*
OPP Mission: To lead policy development and analysis, strategic planning, and evaluation to ensure a prepared and resilient nation before, during, and after public health emergencies and disasters

National Health Security Strategy (NHSS)

Vision

- A nation that is secure and resilient in the face of diverse incidents with health consequences, with people in all communities enjoying a high level of security against threats to their health and well-being

• Goal

- To strengthen and sustain communities' abilities to prevent, protect against, mitigate the effects of, respond to, and recover from incidents with negative health consequences

• Guiding Principles

- Strategic alignment
- Evidence-based practice
- Continuous quality improvement
- Community involvement
- Maximum benefit

NHSS is a national strategy that enlists community partners and shared responsibility among ALL segments of society.

COMMUNITY

Resilience




Office of Policy & Planning

- Strengthen national and international health security by working through domestic and international partnerships to develop policies and plans for coordination and mutual assistance during public health emergencies; and support domestic and international capacity building programs under the International Health Regulations Framework and other national and global health security efforts. Promote the resilience of U.S. communities at the national, state, and local levels by implementing initiatives, policies, and programs to strengthen health systems and to ensure that the behavioral and medical needs of at-risk populations are addressed during public health emergencies



Office of Policy & Planning

- Lead the development and implementation of plans for chemical, biological, radiological/nuclear agents, and/or diseases with pandemic potential threats, biosafety/biosecurity strategies, and establishment of requirements and policies for medical countermeasure availability and access to increase the U.S. capacity to respond to public health emergencies. Develop national strategies and evaluate public health preparedness, response and recovery activities, and promote evidence-based corrective actions through policy, executive or legislative authorities.



Disaster Leadership Group (DLG)

- At the request of the ASPR, HHS senior leaders convene to share information and make policy decisions related to public health emergencies, incidents, or events. ASPR is responsible for advising the Secretary of HHS on any recommendations that result from these discussions. The frequency and duration of DLGs are determined by the needs or requirements of the particular event. Current DLGs include: H7N9, Zika Virus Disease, critical medication shortages. A few examples of topics addressed by past DLGs include: Flint, MI water contamination, Louisiana floods, and Ebola.

ASPR – Other Key Departments

Office of Acquisition Management, Contracts & Grants The Office of Acquisitions Management, Contracts and Grants (AMCG) provides ASPR with acquisition support to prepare and respond to the adverse health emergencies and disasters and provides contractual support to ASPR. Office of the Chief Operating Officer The Office of the Chief Operating Officer (COO) is responsible for ensuring effective stakeholder communication and administrative management. As the focal point for external communications, the Office of the Chief Operating Officer is responsible for ensuring the effective management of public affairs, online governance, and strategic partnerships. Office of Financial Planning and Analysis The Office of Financial Planning and Analysis (OFPA) is responsible for providing expertise and analysis in the formulation and implementation of policies, procedures, and operational strategies that ensure efficient and effective allocation and utilization of program resources in support of ASPR's mission.



ASPR on the Web



PHE.gov:
www.phe.gov



PHE.gov Newsroom:
www.phe.gov/newsroom



Flickr:
www.flickr.com/phegov



ASPR

TRACIE:asprtracie.

hhs.gov

Resilient People. Healthy Communities. A Nation Prepared.



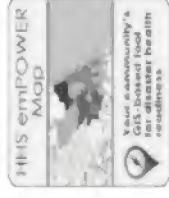
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www.facebook.com/phegov



YouTube:
www.youtube.com/phegov



Twitter:
twitter.com/phegov



HHS emPOWER

Map:www.phe.gov/empow

emmap

A Nation Prepared.



From: HHS Secretary (HHS/IOS)
Sent: 3 Feb 2017 20:44:05 +0000
To: Cochran, Norris (HHS/ASFR);Robinson, Wilma (HHS/IOS);Stannard, Paula (HHS/IOS);Leggitt, Lance (HHS/IOS);Flick, Heather (HHS/IOS);Clark, Timothy (HHS/IOS);Schaefer, Nina (HHS/IOS);Schuchat, Anne MD (CDC/OD);Wynne, Maggie (HHS/IOS);Giles, Karen (HHS/OS);Horska, Katerina (HHS/IOS);Davis, Jeffrey (HHS/OGC)
Cc: Hawkins, Jamar (HHS/OS);Moore, Hannah (OS/IOS);Grove, Matthew R. (HHS/OS);Bowles, Jamil (HHS/IOS);Zebley, Kyle (HHS/IOS)
Subject: CDC Briefing for Beachhead Team Members [MATERIALS ATTACHED]
Attachments: CDC Beachhead Team materials Feb 3 Final.docx

Materials:



Purpose: Continuation meeting with Beachhead Team members. Please be sure to bring anything urgent regarding the Paper Work Reduction (PRA) to these meetings. Contact Dr. Wilma Robinson should you have any questions.

Participants:

Norris Cochran
Paula Stannard
Heather Flick
Lance Leggitt
Nina Schaefer
Wilma Robinson
Timothy Clark
Maggie Wynne
Dr. Anne Schuchat

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From: HHS Secretary (HHS/IOS)
Sent: 24 Feb 2017 17:29:42 +0000
To: HHS Secretary (HHS/IOS);Cochran, Norris (HHS/ASFR);Robinson, Wilma (HHS/IOS);Stannard, Paula (HHS/IOS);Leggitt, Lance (HHS/IOS);Flick, Heather (HHS/IOS);Clark, Timothy (HHS/IOS);Schaefer, Nina (HHS/IOS);Schuchat, Anne MD (CDC/OD);Wynne, Maggie (HHS/IOS);Giles, Karen (HHS/OS);Hawkins, Jamar (HHS/OS);Moore, Hannah (OS/IOS);Grove, Matthew R. (HHS/OS);Bowles, Jamil (HHS/IOS);Horska, Katerina (HHS/IOS);Davis, Jeffrey (HHS/OGC);Zebley, Kyle (HHS/OS/OGA);Brooks, John (HHS/IOS)
Cc: Agnew, Ann (HHS/IOS)
Subject: CDC Briefing for New Policy Team [MATERIALS ATTACHED]
Attachments: CDC Week Ahead Report - 03-09-2017.docx, Supplemental Info_CDC Week Ahead Report - 03-09-2017.docx

MATERIALS:



Purpose: Continuation meeting with new Policy Team. Please be sure to bring anything urgent regarding the Paper Work Reduction (PRA) to these meetings. Contact Dr. Wilma Robinson should you have any questions.

Participants:

Norris Cochran
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From: HHS Secretary (HHS/IOS)
Sent: 24 Feb 2017 17:28:36 +0000
To: HHS Secretary (HHS/IOS);Cochran, Norris (HHS/ASFR);Robinson, Wilma (HHS/IOS);Stannard, Paula (HHS/IOS);Leggitt, Lance (HHS/IOS);Flick, Heather (HHS/IOS);Clark, Timothy (HHS/IOS);Schaefer, Nina (HHS/IOS);Schuchat, Anne MD (CDC/OD);Wynne, Maggie (HHS/IOS);Giles, Karen (HHS/OS);Secretary Conference Room (HHS);Hawkins, Jamar (HHS/OS);Moore, Hannah (OS/IOS);Grove, Matthew R. (HHS/OS);Bowles, Jamil (HHS/IOS);Horska, Katerina (HHS/IOS);Davis, Jeffrey (HHS/OGC);Zebley, Kyle (HHS/IOS);Brooks, John (HHS/IOS)
Cc: Agnew, Ann (HHS/IOS)
Subject: CDC Briefing for New Policy Team [MATERIALS ATTACHED]
Attachments: CDC Week Ahead Report - 03-02-2017.docx, CDC_HHS Week Ahead Report_Supplemental Information - 03.02.17.docx

MATERIALS:



Purpose: Continuation meeting with new Policy Team. Please be sure to bring anything urgent regarding the Paper Work Reduction (PRA) to these meetings. Contact Dr. Wilma Robinson should you have any questions.

Participants:

Norris Cochran
Paula Stannard
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From: HHS Secretary (HHS/IOS)
Sent: 8 Mar 2017 23:29:19 +0000
To: Cochran, Norris (HHS/ASFR);Robinson, Wilma (HHS/IOS);Stannard, Paula (HHS/IOS);Leggitt, Lance (HHS/IOS);Flick, Heather (HHS/IOS);Clark, Timothy (HHS/IOS);Schaefer, Nina (HHS/IOS);Schuchat, Anne MD (CDC/OD);Wynne, Maggie (HHS/IOS);Giles, Karen (HHS/OS);Hawkins, Jamar (HHS/OS);Moore, Hannah (OS/IOS);Grove, Matthew R. (HHS/OS);Bowles, Jamil (HHS/IOS);Horska, Katerina (HHS/IOS);Davis, Jeffrey (HHS/OGC);Zebley, Kyle (HHS/OS/OGA);Brooks, John (HHS/IOS)
Cc: Agnew, Ann (HHS/IOS)
Subject: CDC Briefing for New Policy Team [MATERIALS ATTACHED]
Attachments: CDC Week Ahead Report - 03-09-2017.docx, Supplemental Info_CDC Week Ahead Report - 03-09-2017.docx

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From: HHS Secretary (HHS/IOS)
Sent: 1 Mar 2017 22:27:24 +0000
To: Cochran, Norris (HHS/ASFR);Robinson, Wilma (HHS/IOS);Stannard, Paula (HHS/IOS);Leggitt, Lance (HHS/IOS);Flick, Heather (HHS/IOS);Clark, Timothy (HHS/IOS);Schaefer, Nina (HHS/IOS);Schuchat, Anne MD (CDC/OD);Wynne, Maggie (HHS/IOS);Giles, Karen (HHS/OS);Secretary Conference Room (HHS);Hawkins, Jamar (HHS/OS);Moore, Hannah (OS/IOS);Grove, Matthew R. (HHS/OS);Bowles, Jamil (HHS/IOS);Horska, Katerina (HHS/IOS);Davis, Jeffrey (HHS/OGC);Zebley, Kyle (HHS/IOS);Brooks, John (HHS/IOS)
Cc: Agnew, Ann (HHS/IOS)
Subject: CDC Briefing for New Policy Team [MATERIALS ATTACHED]
Attachments: CDC Week Ahead Report - 03-02-2017.docx, CDC_HHS Week Ahead Report_Supplemental Information - 03.02.17.docx

MATERIALS:



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Dr. Anne Schuchat

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From: HHS Secretary (HHS/IOS)
Sent: 15 Mar 2017 21:35:12 +0000
To: Cochran, Norris (HHS/ASFR); Robinson, Wilma (HHS/IOS); Stannard, Paula (HHS/IOS); Leggitt, Lance (HHS/IOS); Flick, Heather (OS/OGC); Clark, Timothy (HHS/IOS); Schaefer, Nina (HHS/IOS); Schuchat, Anne MD (CDC/OD); Wynne, Maggie (HHS/IOS); Giles, Karen (HHS/OS); Hawkins, Jamar (HHS/OS); Moore, Hannah (OS/IOS); Grove, Matthew R. (HHS/OS); Bowles, Jamil (HHS/IOS); Horska, Katerina (HHS/IOS); Davis, Jeffrey (HHS/OGC); Zebley, Kyle (HHS/OS/OGA); Brooks, John (HHS/IOS); Lapinski, Mary-Sumpter (HHS/IOS)
Cc: Agnew, Ann (HHS/IOS); Moughalian, Jen (HHS/ASFR)
Subject: CDC Briefing for New Policy Team [MATERIALS ATTACHED]
Attachments: CDC Week Ahead Report - 03-16-2017.docx, CDC Week Ahead Report - 03-16-2017 Supplemental Documents.docx

Purpose: Continuation meeting with new Policy Team. Please be sure to bring anything urgent regarding the Paper Work Reduction (PRA) to these meetings. Contact Dr. Wilma Robinson should you have any questions.

MATERIALS:



Participants:

Norris Cochran
Paula Stannard
Heather Flick
Lance Leggitt
Nina Schaefer
Timothy Clark
Maggie Wynne
John Brooks
Mary-Sumpter Lapinski
Ann Agnew
Wilma Robinson
Jeff Davis
Dr. Anne Schuchat – in person
Sherri Berger - VTC

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of the Freedom of Information Act

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of the Freedom of Information Act

From: Office of the Executive Secretary Master Calendar (HHS/OS)
Sent: 2 Oct 2017 21:30:20 +0000
To: Caliguiri, Laura (HHS/IOS);Brady, Will (HHS/IOS);Stannard, Paula (HHS/IOS);Bell, Kathryn (HHS/IOS);Agnew, Ann (HHS/IOS);Malliou, Ekaterini (OS/IOS);Kadlec, Robert (OS/ASPR/IO);Gabriel, Edward (OS/ASPR/IO);Meekins, Chris (OS/ASPR/IO);Curren, Stephen (OS/ASPR/OEM);Fantinato, Jessica (OS/ASPR/OEM);Wolf, Laura (OS/ASPR/OEM);Todd, Nickol (OS/ASPR/OEM);Bardis, John (HHS/ASA);Cordova, Jon (OS/ASA);Killoran, Beth (OS/ASA/OCIO);Wlaschin, Christopher (OS/ASA);Chua, Julie A. (OS/OCIO);Roeder, Al (OS/ASA/OCIO);Bollerer, Christopher (OS/ASA);Lawrence, Courtney (HHS/ASL);Davis, Jeffrey (HHS/OGC);Flick, Heather (OS/OGC);Mac Gabhann, Lucy (HHS/OGC);Schmoyer, Michael (OS/OSSI);Haseltine, Amy (OS/ASA/OCIO)
Cc: Hawkins, Jamar (HHS/OS);Stephan, Briana (OS/ASPR/IO);Williams, Rasheed (HHS/IOS);Andrews, Sean (OS/ASPR/IO)
Subject: Cybersecurity - DHS
Attachments: FINAL DRAFT - DHS NCCIC and HHS HCCIC CONOPS v0.7.docx, Signed MOA.PDF, Talking Points from CONOPS Efforts (DHS HHS) - 08_07_2017 v4.docx

Purpose

Discuss the HHS and DHS cybersecurity partnership, including:

- (b)(5)
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- (b)(5)

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Agenda

Draft CONOPS, MOU, Draft Talking Points – Beth Killoran, Christopher Wlaschin (ASA)

Papers, Attached



Participants

Deputy Secretary's Office: Laura Caliguiri, Will Brady

Counselors: Paula Stannard, Kathryn Bell

Exec. Sec.: Ann Agnew, Ekaterini (Kat) Malliou

ASPR: Robert Kadlec, Edward Gabriel, Chris Meekins, Stephen Curren, Jessica Fantinato, Laura Wolf, Nicole Todd,

ASA: John Bardis, Jon Cordova, Beth Killoran, Christopher Wlaschin, Julie Chua, Al Roeder, Chris Bollerer

ASL: Courtney Lawrence

OGC: Jeff Davis, Heather Flick, Lucy Mac Gabhann

OSSI: Michael Schmoyer

Contact

Dr. Ekaterini (Kat) Malliou [202-690-6875, Ekaterini.Malliou@hhs.gov]

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MEMORANDUM OF AGREEMENT

BETWEEN

**THE DEPARTMENT OF HOMELAND SECURITY,
OFFICE OF CYBERSECURITY AND COMMUNICATIONS**

AND

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF SECURITY AND STRATEGIC INFORMATION**

1. PARTIES. The Parties to this Memorandum of Agreement (MOA) are the Department of Homeland Security (DHS), Office of Cybersecurity and Communications (CS&C) and Department of Health and Human Services (HHS), Office of Security and Strategic Information (OSSI), collectively referred to in this MOA as the "Parties".

2. AUTHORITY. This Agreement is authorized under the provisions of:

- a. Cybersecurity Information Sharing Act of 2015
- b. Federal Information Security Modernization Act of 2014 (PL 113-283)
- c. Executive Order (EO) 13800 Improving Cybersecurity
- d. EO 13691: Promoting Private Sector Cybersecurity Information Sharing
- e. Executive Order (EO) 13800 Improving Cybersecurity
- f. Executive Order (EO) 12333: United States Intelligence Activities, as amended
- g. Presidential Policy Directive 41 (PPD-41): United States Cyber Incident Coordination
- h. Homeland Security Act, 6 U.S.C. §§ 112(b)(2), 121(f)
- i. Executive Order (EO) 13636 Improving Critical Infrastructure Cybersecurity
- j. Presidential Policy Directive 21: Critical Infrastructure Security and Resilience
- k. 77 FR 71004 (Nov. 28, 2012)
- l. 74 FR 57679 (Nov. 09, 2009)

3. PURPOSE. The purpose of this MOA is to document approval of, and terms and conditions for the assignment of employee(s) of HHS to CS&C's National Cybersecurity and Communications Integration Center (NCCIC). This Agreement addresses the relationship between operational (i.e. daily), administrative, and management control concerning the assignment(s). Details regarding duties, employment status, type and length of assignment, funding, and additional particulars of individual assignee under this MOA will be outlined in Appendices to this MOA, executed by the representatives of the Parties and each assignee. A separate appendix shall be executed for each assignee under this MOA.

As used in this MOA, an 'assignee' is an employee of OCIO or OSSI working on assignment in DHS spaces, performing activities in support of HHS's mission and under HHS's authorities, without a change of position from the agency by which he or she is employed. Liaisons are treated as assignees.

4. TERMS AND CONDITIONS.

- a. Staff: HHS agrees to assign the individual(s) listed in Appendices to this MOA as assignees to CS&C (NCCIC).

- b. Dissemination of DHS Information: DHS and HHS agree that HHS assignees to CS&C may not disseminate to HHS or otherwise outside of CS&C any information they learn during the course of their assignment pertaining to DHS operations without the express approval of the relevant Division Director or an individual designated in writing by the specified Division Director. Such information, when authorized for disclosure to HHS must continue to be marked as a DHS product.
- c. Funding: This assignment is non-reimbursable. The assignment is non-reimbursable because of the inherent mission benefits to HHS reporting requirements. The reporting tasks are similar or related to matters ordinarily handled by HHS and will aid OSSI and NCCIC team members in sharing information in a timely manner. The liaison will assist OSSI in carrying out its cyber mission to detect and mitigate cyber threats across the Department's cyber infrastructure, protect the Department from the loss of proprietary, sensitive and/or national security information, as well as, address the sector-specific agency responsibilities for the Healthcare and Public Health and the Food and Agriculture sectors by enabling OSSI to access relevant information at the NCICC in real time and maintain situational awareness of the common operational picture for cyberspace maintained by the NCCIC. It will also enhance OSSI's knowledge of related NPPD operations and missions which will promote coordination efforts. The information reporting and the integration process will assist OSSI in creating or refining current reporting functions and processes and streamlining some operational capabilities.
- d. Personnel & Administrative Responsibility: DHS and HHS will share administrative control and responsibility for the assignee(s) sent to CS&C. Administrative responsibility will be divided as follows:
 - i. Supervision. CS&C shall assign an individual to serve as the assignee's point of contact ("the CS&C Designated Manager"). For assignees, the CS&C Designated Manager shall serve as the point of contact and shall operationally oversee the assignee's activities, but shall not function as the Assignee's supervisor. The assignee's OSSI supervisor of record will remain the supervisors of record.
 - ii. Time and Attendance. Time and Attendance actions and processes will be the responsibility of the assignee's supervisor at OSSI. The CS&C Designated Manager or Designee will provide information via email to the designated HHS point of contact on recorded time for each pay period to include hours worked and any leave taken. In the event overtime is required, the OSSI is responsible for compensating the assignee(s) for all ordered, approved, and worked overtime as required by the overtime pay rules applicable to the assignee(s).
 - iii. Travel. CS&C will pay for all official travel undertaken on behalf of CS&C in accordance with the federal travel regulations. Such travel must be approved in advance by CS&C designated management, and notification provided to the CS&C Manager or designees. Travel vouchers shall be submitted within five (5) business days after completion of travel. For travel required by OSSI, OSSI will be responsible for reimbursing the assignee.
 - iv. Leave. For assignments, the OSSI supervisor will process all leave requests.
 - v. Evaluation. Official performance evaluations and performance plans remain the responsibility of OSSI. The CS&C Designated Manager, as needed or desired by OSSI, will provide evaluative comments for the record at the end of each applicable evaluation period.

- vi. Security Clearances. Each individual assigned to CS&C (NCCIC) is required to have a Top Secret Sensitive Compartmented Information (TS/SCI) clearance. If an individual is unable to obtain the required level of access to classified information or his/her access is suspended or revoked for any reason, NCCIC retains the right to immediately terminate the assignment of that individual. Personnel must adhere to DHS Instruction 121-01-011, The DHS Administrative Security Program, DHS Instructional Handbook 121-01-007, The DHS Personnel Suitability and Security Program, CS&C Security Federal Detailee Suitability Process, and direction provided by his/her office.
- vii. Conduct. CS&C reserves the right to return an assignee to his/her home Agency if the assignee engages in alleged misconduct.
- viii. Performance Awards and Pay Increases. OSSI will remain the approving and funding authority for performance awards, including quality step increases and promotions. The CS&C Designated Manager will provide justification and recommendation regarding any recommended performance awards.
- ix. Removal for Poor Performance. The CS&C Designated Manager reserves the right to terminate the assignment of any individual due to poor performance.

5. POINTS OF CONTACT.

CS&C:

Name: Linda Ward or TBD

Position Title: Chief of Staff

Organization: Office of Cybersecurity and Communications

Office Phone: 703-235-5192

Email Address: CS&C ExecSec@hq.dhs.gov

HHS OSSI:

Name: Brett Maycock

Title: Associate Deputy Assistant Secretary (Acting)

Organization: Office of Security and Strategic Information

Office: 202-205-0551

Cell: 202-394-6084

Email: Brett.Maycock@hhs.gov

6. EFFECTIVE DATE. This MOA is effective upon the date of the final signature by representatives of both Parties.

7. MODIFICATION. This MOA may be modified in writing upon the mutual written consent of the Parties.

8. TERMINATION. The terms of this MOA, as modified with the consent of both Parties, will remain in effect until terminated. Either Party upon 30 days written notice to the other Party may terminate this MOA.

9. COST. This MOA does not obligate any funds and is subject to the availability of funds.

10. OTHER PROVISIONS.

- a. Severability: Nothing in this MOA or any appendices shall be construed to conflict with current law, regulation, or directive of the HHS or DHS. If a term of this MOA is inconsistent with such authority, then that term shall be invalid, but the remaining terms and conditions of this MOA will remain in full force and effect.
- b. Rights and Benefits: Nothing in this MOA is intended to diminish or otherwise affect the authority of any Agency to carry out its statutory, regulatory or other official functions, nor is it intended to create any right or benefit, substantive or procedural, enforceable at law by any party against the United States, its agencies or offices, State agencies or officers carrying out programs authorized under Federal law, or any other person.
- c. Dispute Resolution: Should disagreements arise on the interpretation of the provisions of this MOA or appendices and/or revisions thereto, that cannot be resolved at the operating level, the area(s) of disagreement shall be stated in writing by each Party and presented to the other Party for consideration. If agreement or interpretation is not reached within 30 days, the Parties shall forward the written presentation of the disagreement to respective higher officials for appropriate resolution.
- d. Review: The Parties agree to review this MOA periodically to evaluate its effectiveness performance, ensure adequate identification of support requirements, and to make any necessary changes. Additional reviews may be conducted if deemed necessary upon mutual agreement of the Parties.

11. APPROVED BY:

Danny Toller
Assistant Secretary (Acting)
Office of Cybersecurity and Communications
National Protection and Programs Directorate
U.S. Department of Homeland Security

Date

TBD
Director
Human Resources Management
National Protection and Programs Directorate
U.S. Department of Homeland Security

Date

Michael Schmoyer
Deputy Assistant Secretary for Security, Intelligence & Counterintelligence
Secretary's Senior Intelligence Official
Office of Security and Strategic Information (OSSI)
U.S. Department of Health and Human Services

Date

Beth Anne B Killoran

Beth Anne Killoran
Deputy Assistant Secretary for Information Technology
Chief Information Officer
Office of the Chief Information Officer (OCIO)
U.S. Department of Health and Human Services

8/30/2017

Date

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Withheld pursuant to exemption

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of the Freedom of Information Act

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of the Freedom of Information Act

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Withheld pursuant to exemption

(b)(5)

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Page 217 of 270

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information Act

From: Tignor, Beth (HHS/IOS) on behalf of Secretary Scheduler (OS/IOS)
Sent: 8 Nov 2017 22:36:55 +0000
To: Brady, Will (HHS/IOS);DeputySecretary (OS/IOS);EDH (OS/IOS);Lagomarsino, Katie (OS/IOS);Leggitt, Lance (HHS/IOS);Martinez, Cecilia (OS/IOS);Moreno, Rafael (HHS/ASA);Olson, Carolyn (OS/IOS);Skrzycki, Kristin (HHS/IOS);Tignor, Beth (HHS/IOS);Trueman, Laura (HHS/IEA);Norton, Jane (OS/IEA);Severino, Roger (HHS/OCR);Stannard, Paula (HHS/IOS);Royce, Shannon (OS/CFBNP);Butterfield, Justin (HHS/OCR);Bell, March (HHS/OCR);Stimson, Brian (HHS/OGC)
Subject: EDH to meet with the Little Sisters of the Poor
Attachments: 11 9 17 Briefing Memo Little Sisters of the Poor Meeting.docx

Lead: IEA,





DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

To: Secretary Eric D. Hargan
Through: Jane E. Norton
From: Intergovernmental & External Affairs
Subject: Meeting with Attorneys and Plaintiffs on HHS Mandate
Date: Wednesday, November 8, 2017

Meeting Details:

Date: Thursday, November 9, 2017
Time: 10:30am – 11:00am EST
Location: 610-F
Participants:

External

Mark Reinzi, Senior Counsel, Becket Fund
Plaintiff - Sister Lorraine Marie Maguire, Mother Provincial, head of the
Little Sisters of the Poor
Kevin Theriot, Alliance Defending Freedom
Plaintiff - Jeanne Mancini (March for Life)
Martin Nussbaum, Partner, Lewis, Roca, Rotherberger, Christie etc.
Plaintiff Catholic Benefits Association (may not be in attendance)

Department of Justice

TBD

HHS Staff

Roger Severino, OCR
March Bell, OCR
Justin Butterfield, OCR
Paula Stannard, Senior Counselor
Jane Norton, IEA
Laura Trueman, IEA
Shannon Royce, IEA

Topic: The attorneys and their plaintiffs would like to discuss the impact that the HHS contraception mandate has had on their organizations – practically and financially -- and their need to move forward by having this litigation fully resolved.

What You Will Hear:

(b)(5)

(b)(5)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

(b)(5)

Attachments:

1. Meeting Participant Bios

**Attachment 1. Participant Bios****Mark Reinzi**
Becket Fund

Mark joined the Becket team in 2011 and splits his time as an associate professor at The Catholic University of America, Columbus School of Law. Mark teaches constitutional law, religious liberty, torts, and evidence. He has been voted Teacher of the Year three years in a row by the Law School's Student Bar Association.

Mark has broad experience litigating First Amendment religious exercise and free speech cases. He has represented the winning parties in a variety of Supreme Court First Amendment cases including [Hobby Lobby, Little Sisters, Wheaton College, and Holt]. In January 2014, Mark argued before the Supreme Court in *McCullen v. Coakley*, a First Amendment challenge to a Massachusetts speech restriction outside of abortion clinics. The Justices ruled in favor of his clients 9-0. Mark also led a successful eight-year litigation battle against Governor Blagojevich's effort to force religious pharmacists to distribute the morning-after and week-after pills.

Prior to joining Becket, Mark served as counsel for the litigation department and the intellectual property litigation practice group of WilmerHale LLP. His practice focused on complex civil and appellate litigation with a particular emphasis on intellectual property and First Amendment issues. Prior to joining WilmerHale, he served as law clerk to the Hon. Stephen F. Williams, senior circuit judge for the U.S. Court of Appeals for the D.C. Circuit. Prior to that, Mark was an editor of the *Harvard Law Review*, and earned his J.D. from Harvard Law School and B.A. from Princeton University, both with honors.

**Sister Lorraine Marie Maguire**
Mother Provincial of the Baltimore Little Sisters of the Poor.

She has been the lead on the case and said: *"As Little Sisters of the Poor, we offer the neediest elderly of every race and religion a home where they are welcomed as Christ. We perform this loving ministry because of our faith and cannot possibly choose between our care for the elderly poor and our faith, and we shouldn't have to," said Sr. Lorraine Marie Maguire, Mother Provincial of the Little Sisters of the Poor. "All we ask is that our rights not be taken away. The government exempts large corporations, small businesses, and other religious ministries from what they are imposing on us – we just want to keep serving the elderly poor as we have always done for 175 years."*



Jeanne Mancini
President of the March for Life Education and Defense Fund

Jeanne was appointed to the role of President of the March for Life Education and Defense Fund in the fall of 2012. In this capacity she proudly directs the small non-profit organization committed to restoring a culture of life in the United States, most notably through the annual March for Life in Washington, D.C., held on the anniversary of *Roe v. Wade*.

Previously Jeanne worked with the Family Research Council (FRC), where she focused on issues related to the inherent dignity of the human person, including abortion, women's health, and end-of-life issues. Prior to FRC Jeanne worked for the U.S. Department of Health and Human Services in the Office of the Secretary. Her federal government experience includes global health policy, as well as domestic and international health care issues. Before working in public policy, Jeanne worked for the Catholic Church in a variety of positions involving educating on life issues, human sexuality, marriage, and family.

Jeanne has made frequent media appearances including interviews on MSNBC, CNN, FOX, ABC, CBS, and others. Jeanne's writings have appeared in *The New York Times*, *U.S. News and World Report*, *USA Today*, the *Washington Post* and numerous others publications.

Jeanne holds an undergraduate degree in psychology from James Madison University and a Master's degree in the theology of marriage and family from the Pope John Paul II Institute for Studies on Marriage and Family. Jeanne resides in northern Virginia with her husband, David.



Martin Nussbaum
Co-founder and co-chair of the Religious Institutions Group in the practice of Lewis, Roca, Rothgerber, Christie

Martin is based in Colorado and is the co-founder and co-chair of the Religious Institutions Group in the practice of Lewis, Roca, Rothgerber, Christie. He represents churches, denominations, religious schools, and a host of other ministries. While he serves as general counsel for many, he also serves as trial counsel, First Amendment counsel, amicus counsel, and consulting counsel in trial and appellate courts and before legislatures around the country. In 2016, Martin filed briefs in four United States Supreme

Court religious liberty cases.

Representative clients include: Catholic archdioceses and dioceses of Boston, Bridgeport, Cheyenne, Colorado Springs, Denver, Jackson, Kansas City, Portland, Pueblo, and Los Angeles; Knights of Columbus; Dr. James Dobson's Family Talk; Church of Jesus Christ of Latter-day Saints; Mother Angelica and Our Lady of the Angels Monastery; Association of Christian Schools International; Chabad-Lubavitch of Michigan; Catholic Benefits Association; Catholic Insurance Company;



Christian Employers Alliance; North American Lutheran Church; Evangelical Christian Credit Union; Father Flanagan's Boys Town; various Episcopal Church dioceses; Colorado Christian University, First United Methodist Church of Colorado Springs; Colorado Springs Christian Schools; New Life Church; Catholic Charities of Pueblo.




Kevin Theriot

Senior Counsel and Vice President of the Center for Life with the Alliance Defending Freedom Fund

Kevin serves as senior counsel and vice president of the Center for Life with Alliance Defending Freedom, where he directs the work of team members working to overturn *Roe v. Wade*, defend pro-life speech, and battle against physician-assisted suicide.

Since joining Alliance Defending Freedom in 2003, Theriot has been successful as lead counsel or co-counsel in numerous cases preserving religious freedom. In *Women's Health Link v. City of Ft. Wayne, Ind.*, he defended the freedom of a crisis pregnancy center to access an advertising forum in city buses. In *The Children First Foundation v. Martinez*, he received a favorable ruling eliminating unconstitutional discrimination against "Choose Life" auto license plates. He also successfully defended the First-Amendment-protected freedom of federal employees to express their faith at work in *Lister v. Defense Logistics Agency*.

From: Tignor, Beth (HHS/IOS) on behalf of Secretary Scheduler (OS/IOS)
Sent: 9 Nov 2017 12:59:58 +0000
To: Brady, Will (HHS/IOS);DeputySecretary (OS/IOS);EDH (OS/IOS);Lagomarsino, Katie (OS/IOS);Leggitt, Lance (HHS/IOS);Martinez, Cecilia (OS/IOS);Moreno, Rafael (HHS/ASA);Olson, Carolyn (OS/IOS);Skrzycki, Kristin (HHS/IOS);Tignor, Beth (HHS/IOS);Trueman, Laura (HHS/IEA);Norton, Jane (OS/IEA);Severino, Roger (HHS/OCR);Stannard, Paula (HHS/IOS);Royce, Shannon (OS/CFBNP);Butterfield, Justin (HHS/OCR);Bell, March (HHS/OCR);Stimson, Brian (HHS/OGC)
Subject: EDH to meet with the Little Sisters of the Poor
Attachments: 11 9 17 Briefing Memo Little Sisters of the Poor Meeting.docx

Lead: IEA, 
Attendees:

Mark Reinzi, Senior Counsel, Becket Fund
Mother Provincial, head of the Little Sisters of the Poor
Martin Nussbaum, Partner, Lewis, Roca, Rotherberger, Christie, represented the Catholic Benefits Association in suit against HHS contraception mandate.

Department of Justice

Roger Severino will be contacting the DOJ attorney who works on these cases to join us. Name coming.

Staff

Roger Severino
Paula Stannard
Matt Bowman (if he is not recused)
Laura Trueman
Shannon Royce

Meeting Focus – Discuss the infringement against religious liberty and conscience imposed by HHS mandate.

From: Tignor, Beth (HHS/IOS) on behalf of Secretary Scheduler (OS/IOS)
Sent: 3 Jan 2018 21:52:02 +0000
To: Brady, Will (HHS/IOS); Caliguiri, Laura (HHS/IOS); Deputy Secretary (OS/IOS); EDH (OS/IOS); Leggitt, Lance (HHS/IOS); Martinez, Cecilia (OS/IOS); Moreno, Rafael (HHS/ASA); Skrzycki, Kristin (HHS/IOS); Tignor, Beth (HHS/IOS); Olson, Carolyn (OS/IOS); Lagomarsino, Katie (OS/IOS); Holden, Ronald (OS/IOS); Severino, Roger (HHS/OCR); Stannard, Paula (HHS/IOS); Smith, Christopher (HHS/ASPA); Smith, Gavin (OS/ASPA); Brennan, Patrick (OS/ASPA); Pasch, David (OS/ASPA)
Subject: EDH to Visit OCR
Attachments: rev_Secretary Cover Memo Template(OCR).docx, as of 351_Short Bio (2).docx, Hargan Meeting - Drop in.docx





DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

To: Acting Secretary Eric Hargan

From: Roger Severino, Director,
Office for Civil Rights

Subject: OCR Site Visit

Date: Thursday, January 4, 2018

Event Details:

Date: Thursday, January 4, 2018

Time: 4:00 PM – 4:30 PM

Location: Room 515F – Director’s Conference Room HHH Building

HHS Staff: *See Below*

Who requested this event:

Office of the Secretary

Topic:

Meet and Greet with OCR Leadership Staff and discussion on the work happening at OCR

Objective:

For OCR Staff to get the opportunity to meet with Acting Secretary Hargan and discuss the important work happening at OCR

List of Attendees/Participants:

Roger Severino – Director of OCR

March Bell – Chief of Staff

Robinsue Frohboese -- Principal Deputy Director

Steve Novy – Deputy Director, Operations and Resources Division

Louis Brown – Deputy Director, Civil Rights (Acting)

Marissa Gordon-Nguyen – Deputy Director, Health Information Privacy (Acting)

Justin Butterfield – Senior Advisor to the Director

Maya Noronha – Special Advisor to the Director



Meeting / Event Agenda:

4:00 - 4:01 PM - Secretary welcomed by Director Roger Severino

4:01 – 4:21 PM - Leadership Roundtable – 5 minute updates and the year ahead.

4:21 – 4:26 PM - Wrap up by Robinsue Frohboese

Background:

Acting Secretary Hargan will meet with the OCR Leadership Team from 4:00 PM until 4:30 PM.

The Acting Secretary has met recently for a Q and A with the entire OCR headquarters staff.

Attachments:

1. Short Summaries of Accomplishments and Future Plans
2. Leadership Biographies

Office for Civil Rights – Leadership Bios

Roger Severino – Director

Roger Severino is the Director of the Office for Civil Rights at the U.S. Department of Health and Human Services. Prior to joining the Department, Mr. Severino served as Director of the DeVos Center for Religion and Civil Society in the Institute for Family, Community, and Opportunity at The Heritage Foundation.

Before joining Heritage in 2015, Mr. Severino was a trial attorney for seven years in the Department of Justice's Civil Rights Division where he enforced the Fair Housing Act, the Religious Land Use and Institutionalized Persons Act, and Title II and Title VI of the Civil Rights Act of 1964.

He has litigated cases under sex, race, national origin, religion, disability, and familial status discrimination and served as the Housing and Civil Enforcement Section's E-discovery officer as well as attorney advisor to the fair housing testing program.

Mr. Severino was previously chief operations officer and legal counsel for the Becket Fund for Religious Liberty.

Mr. Severino holds a J.D. from Harvard Law School, received a master's degree in public policy, with highest distinction, from Carnegie Mellon University, and has a bachelor's degree in business from the University of Southern California, where he was a National Merit Scholar.

March Bell, Chief of Staff

Bell served as Staff Director and Chief Counsel for the U.S. House of Representative Select Panel on Infant Lives which produced a 440 page report and 14 criminal referrals on the fetal tissue industry.

During the Bush Administration, Bell served as Senior Counsel for Trafficking in Persons in the Civil Rights Division of the U.S. Department of Justice which involved setting up 42 US Trafficking Task Forces and conducting training of judges, prosecutors and police in 35 different countries.

Bell has extensive professional experience in complex litigation and investigations into organized crime, terrorism, financial fraud, asset tracing, and human trafficking. A graduate of Pepperdine Law School, Bell began his legal career as Counsel for the United States Senate Subcommittee on Security and Terrorism. He later went on to serve as Counsel for the U.S. House of Representatives Committee on Government Reform and Oversight. Throughout his career he has served in several positions with the U.S. Department of Justice.

Robinsue Frohboese, Principal Deputy Director

During Dr. Frohboese's tenure with OCR since 2000, she has served in a variety of leadership positions, including Acting OCR Director during three Administration transitions. She has provided leadership to support OCR's significant expansion of responsibilities over the years from traditional civil rights to health information privacy and security and, most recently, conscience and religious freedom.

Dr. Frohboese also has led a number of special projects for the Office of the Secretary in which OCR was named as the lead agency, including: spearheading the New Freedom Initiative within HHS and across Federal agencies to implement a government-wide focus on community living for persons with disabilities; serving as the HHS representative for six years on the US Delegation to the United Nations to draft the International Disability Treaty and prepare it for Senate ratification; and working with the Secretary's Office on the Report to the President following the Virginia Tech mass shooting tragedy on steps federal and state government can take to prevent similar tragedies.

Prior to joining OCR, Dr. Frohboese worked for 17 years in the Special Litigation Section for the Civil Rights Division at the U.S. Department of Justice, first as a Senior Trial Attorney and then as a Deputy Chief. She has more than 35 years' experience in health-related civil rights enforcement and policy at grassroots, state, and federal levels. She began her federal career working as a staff attorney for the U.S. Senate's Health, Education, Labor, and Pensions Committee following obtaining a J.D. and Ph.D. from the Law-Psychology Joint Degree Program at the University of Nebraska.

Justin Butterfield - Senior Advisor on HIP and Conscience & Religious Freedom

Justin Butterfield, originally from El Paso, Texas, graduated *summa cum laude* from the University of Texas at El Paso with a B.S. in Electrical Engineering. He then attended Harvard Law School, from which he received his J.D. in 2007. At Harvard, Mr. Butterfield served as the student coordinator for The Veritas Forum and was a member of the Federalist Society and the HLS Christian Fellowship. Following his graduation, Mr. Butterfield worked at a business law firm in El Paso; on a Texas State Supreme Court campaign; and, for the past seven years, as a religious liberties civil rights attorney at Kelly Shackelford's First Liberty Institute outside of Dallas, Texas. Mr. Butterfield has co-authored three scholarly articles, and his writing has appeared in the *Washington Times* and the Billy Graham Evangelistic Association's *Decision Magazine*. Mr. Butterfield is married to Alie Butterfield, and they have two young sons, Jameson and Whitaker.

Maya M. Noronha - Special Advisor on Regulatory and Legislative Reform

Maya M. Noronha advises the OCR Director on its regulatory work and represents OCR to the HHS agency-wide Regulatory Reform Task Force. Prior to OCR, Maya focused on civil rights law and civil justice reform in a number of positions. She litigated redistricting cases involving claims of discrimination on the basis of race, sex, and age in voting, worked at an immigration law reform non-

profit, trained attorneys in election law across the country, advised a Member of Congress on maternity and adoption policy, researched civil justice reform policy at the legal center of a think tank, and advocated for religious liberty and conscience at a public interest legal organization. She received a bachelor of arts in government and a juris doctor from Georgetown University. She published a note on OCR's conscience regulation in the *Georgetown Journal of Legal Ethics*.

Marissa Gordon-Nguyen, JD, MPH - Senior Advisor for HIPAA Policy

Marissa leads OCR's HIPAA privacy and security policy development through rulemaking initiatives and the development of sub-regulatory guidance, as well as advising OCR leadership on a range of health information privacy policy matters and providing technical assistance on aspects of the HIPAA Rules to federal agencies, advisory committees, and Congressional staff. Marissa joined OCR in 2009 as a Health Information Privacy Specialist and Presidential Management Fellow after receiving her Law Degree from Georgetown Law and her Master of Public Health from the Johns Hopkins Bloomberg School of Public Health.

Iliana Peters, JD, LLM - Acting Deputy Director for Health Information Privacy

Iliana oversees and manages all aspects of OCR's health information privacy program, including policy, enforcement, outreach, and audit. Prior to serving as the Acting Deputy Director, Iliana was OCR's Senior Advisor for HIPAA Compliance and Enforcement. In this role, Iliana has been the national lead for OCR enforcement of the HIPAA Rules, and she has worked closely with our regional offices to promote compliance including through resolution agreements and civil monetary penalties. Prior to joining the team in D.C., Iliana worked as an investigator in the Southeast Regional Office in Dallas. Iliana received her law degree from Duke and her Masters in Health Care Law from the University of Houston's Health Law and Policy Institute.

Steve Novy, Deputy Director Operations and Resources Division

Steve joined the HHS team on October 1, 2007, and served in a variety of leadership positions in the Assistant Secretary for Administration until July 2011 when he joined the OCR team. Steve came to HHS from the private sector where he served 5 years as a program manager assisting in the stand-up of United States Northern Command. Prior to entering the private sector, Steve served 30 years in the United States Air Force as a flyer, commander, and staff officer. He retired as the Air Mobility Command Director of Staff in the grade of Colonel. Mr. Novy is a certified Project Management Professional (PMP), completed the Harvard University National Preparedness Leadership Institute, and has a Master of Science in Logistics and Acquisition and a Bachelor of Business Administration from the University of Texas.

Louis Brown - Senior Adviser for Civil Rights to the Director

Louis Brown Jr. serves a senior adviser for civil rights to the Director of the Office of Civil Rights for the U.S. Department of Health and Human Services (HHS). Mr. Brown received his undergraduate degree from Michigan State University and his juris doctorate from Howard University School of Law. Among his professional experience, Mr. Brown has previously worked for a faith based health care organization, as legislative counsel to a California based Congressman on Capitol Hill and his liaison to the U.S. House

Committee on the Judiciary, and as a private practice attorney for a Michigan based law firm where he practiced commercial litigation as well as municipal labor law, assisting in the representation the largest municipality in the state.

Office for Civil Rights Accomplishments and the Year Ahead

The following is a list of select OCR accomplishments for 2017 to inform the Secretary ahead of his meeting with the OCR leadership team on January 4, 2018.

1) **Defending Conscience and Religious Freedom**

- OCR has stood up its **new Conscience and Religious Freedom Division (CRFD)**, including securing highly qualified contract staff. Public announcement planned for next week to include a press release, coalition calls, and media calls.
- OCR dramatically increased its enforcement of conscience protection laws and is currently **conducting eight investigations**, in contrast to the less than ten investigations from all of 2009 to 2016 combined. For example OCR is investigating whether:
 - physicians are being forced to counsel patients on the “benefits” of assisted suicide.
 - California may have coerced pro-life pregnancy resource centers into referring for publicly-funded abortions services (the CA law is the subject of a current SCOTUS case).
 - States are requiring persons to pay for or carry insurance coverage for abortions despite their objections in contravention of the Weldon Amendment.

2) **New Regulatory and Deregulatory Initiatives**

- Placing in clearance a new proposed regulation on HHS’s conscience protection statutes.
- **Proposing repeal the Section 1557 regulation** that redefined sex discrimination to cover gender identity and termination of pregnancy and imposed hundreds of millions to billions of dollars in costs on the health care industry through unnecessary translation notice requirements.
- Drafting a new Common Rule for Title IX of the Education Amendments of 1972 to end confusion over the definition of sex in civil rights laws.

3) **Improved Customer Service**

- **30,000 complaints resolved**, including 8,000 complex matters, and 280 outreach events conducted (all new OCR records). Also over 22,000 telephone inquiries, with translation capability, answered and processed.
- Revamped OCR’s HIPAA Breach Reporting Tool and Portal to empower the public with more timely and relevant information about breaches across the country and their resolution, and removed the permanent “wall of shame” aspect of the prior website.
- Issued timely HIPAA guidance during and after the WannaCry ransomware emergency.

4) **Vigorous and Appropriate Law Enforcement**

- Collected **\$19.4M in civil penalty settlements** under HIPAA in 2017 (with another \$3.5 million likely in January) and established corrective action plans with nine covered entities.
- Entered into high impact resolution agreements with covered entities concerning discrimination on the basis of HIV/AIDS status, access to HHS-funded foster care

proceedings for persons with limited English proficiency (LEP), and discrimination against persons seeking medical care who are deaf or hard of hearing.

5) Using Every Tool to Address the Opioid Crisis

- Issued guidance dispelling myths about HIPAA that have prevented doctors from informing loved ones when a patient overdoses. The Wall Street Journal called it “one of the administration’s most significant policy shifts to combat the nation’s opioid crisis.”
- Coordinating with SAMHSA to ensure persons in recovery from opioid addiction do not face discrimination when receiving treatment due to their disability.

6) Hurricane Response

- Issued timely HIPAA and Civil Rights best practices to assure that the needs of persons with limited English proficiency or disabilities are taken into account and that privacy and safety concerns are properly balanced during dangerous emergencies.

From: Tignor, Beth (HHS/IOS) on behalf of Secretary Scheduler (OS/IOS)
Sent: 4 Jan 2018 13:08:34 +0000
To: Brady, Will (HHS/IOS); Caliguiri, Laura (HHS/IOS); Deputy Secretary (OS/IOS); EDH (OS/IOS); Leggitt, Lance (HHS/IOS); Martinez, Cecilia (OS/IOS); Moreno, Rafael (HHS/ASA); Skrzycki, Kristin (HHS/IOS); Tignor, Beth (HHS/IOS); Olson, Carolyn (OS/IOS); Lagomarsino, Katie (OS/IOS); Holden, Ronald (OS/IOS); Severino, Roger (HHS/OCR); Stannard, Paula (HHS/IOS); Smith, Christopher (HHS/ASPA); Smith, Gavin (OS/ASPA); Brennan, Patrick (OS/ASPA); Pasch, David (OS/ASPA)
Subject: EDH to Visit OCR
Attachments: rev_Secretary Cover Memo Template(OCR).docx, as of 351_Short Bio (2).docx, Hargan Meeting - Drop in.docx



- 4:00 – 4:01 pm EDH arrives at Room 515F greeted by **Director Roger Severino**, and then seated next to **Roger Severino** and **Principal Deputy Director Robinsue Frohboese** (1 min.)
- 4:01 – 4:02 pm **Roger Severino** gives brief opening remarks (1 min.)
- 4:02 – 4:22 pm Leadership Roundtable and questions (20 min.)
- 4:22 – 4:30 pm Closing Remarks by **Robinsue Frohboese** (8 min.)

From: Harrison, Jessica (OS/IOS) on behalf of TPMD1 (OS/IOS)
Sent: 31 Mar 2017 17:29:19 +0000
To: Harrison, Jessica (OS/IOS);Skrzycki, Kristin (HHS/IOS);Twomey, John K. (OS/IOS);Leggitt, Lance (HHS/IOS);Zebley, Kyle (HHS/OS/OGA);Alexander, Thomas (OS/OGA);Lapinski, Mary-Sumpter (HHS/IOS);Stannard, Paula (HHS/IOS);Agnew, Ann (HHS/IOS);Flick, Heather (OS/OGC)
Subject: H7N9 Briefing
Attachments: ASPR BARDA H7N9 Slides.pptx, NIH H7N9 Slides.pptx, CDC H7N9 Slides.pptx, Briefing Paper H7N9.docx

Event Name: H7N9 Briefing

Location:610-F

Time: 11:30-12p

Topic: H7N9 avian influenza virus

Reason: ASPR leadership will facilitate a briefing about the H7N9 avian influenza virus currently circulating in parts of the world. Divisions of the Department will discuss required resources to combat the spread of the virus and develop a vaccine.

(b)(5)

Lead: Paula Stannard and George Korch

Event POC: Name, Cell and email: Jamar.Hawkins@hhs.gov; Dr. Ekaterini Malliou, 202-286-4549, Ekaterini.Malliou@hhs.gov

Attendees: N/A

HHS Staff Attendees:
Chief of Staff: Lance Leggitt
Counselors: Paula Stannard and Mary-Sumpter Lapinski
Exec Sec: Anne Agnew
ASPR: George Korch - Lead Briefer
ASFR: Norris Cochran
OGA: Mitchell Wolfe
OGC: Jeff Davis
ASL: Barbara Clark
NIH: Francis Collins
CDC: Anne Schuchat – By phone
FDA: Stephen Ostroff

Staff:
Exec Sec: Ekaterini Malliou, Jamar Hawkins
ASPR: Edward Gabriel and Rick Bright
ASFR: Jen Moughalian
OGA: Thomas Alexander, Kyle Zebley, Kamran Daravi
OGC: Heather Flick
ASL: Laura Kemper

NIH: Anthony Fauci
FDA: Lu Borio

Remarks: N/A
Press: N/A
Press Contact: N/A

HHS Staff: John Twomey cell (b)(6) john.twomey@hhs.gov

Briefing Materials: attached below

Notes:

Presentation

Timeline: 11:30am – 11:35am – Introduction – George Korch (ASPR), Mitchell Wolfe (OGA)

11:35am – 11:40am – Epidemiology – Anne Schuchat (CDC)

11:40am – 11:45am – Vaccine – Rick Bright (ASPR/BARDA)

11:45am – 11:50am – Clinical Trials – Anthony Fauci (NIH)

11:50am – 11:55am – Funding – Norris Cochran (ASFR)

11:55am – 12:00noon – Questions and Answers





PRE-PANDEMIC INFLUENZA VACCINE STOCKPILE: H7N9 UPDATE

Rick Bright, PhD Director
**Biomedical Advanced Research and Development
Authority (BARDA)**



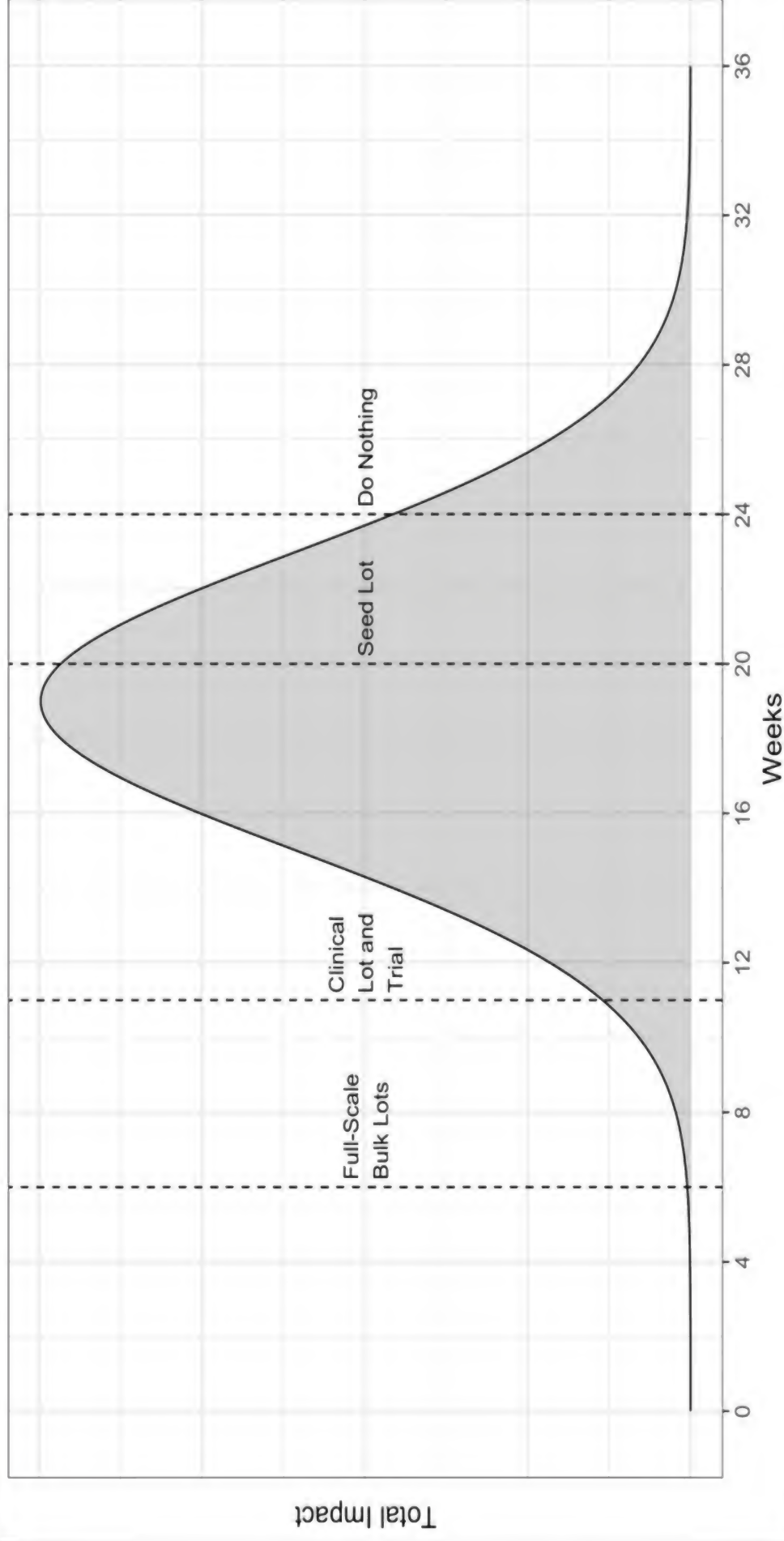
Resilient People. Healthy Communities. A Nation Prepared.

BARDA's National Pre-Pandemic Influenza Vaccine Stockpile: A Risk Based, Metered Approach

- 2005 H5N1 outbreak in SE Asia Established stockpile and met stockpile goals for virus with pandemic potential Implemented innovative Mix and Match program 2009 H1N1 Pandemic 186 M doses of H1N1 vaccine were filled by the manufacturers 120 M doses of bulk adjuvants purchased as a contingency 2012 H3N2v outbreak in the US Clinical lots were made and clinical trials conducted 2013 H7N9 outbreak in China Clinical lots were made and 11 clinical trials conducted 40 M doses of bulk antigen stockpiled



Pre-Pandemic Influenza Vaccine Availability by Risk Management Option




2017 Pre-Pandemic H7N9 Vaccine Stockpile

- BARDA will stockpile 40M doses of H7N9 (2017) vaccine consistent with the National Strategy for Pandemic Influenza and HHS Pandemic Influenza PlanOne-two month window for manufacturing H7N9 starts in June (Vaccine manufacturers prioritize seasonal vaccines)

**Place
order:**

Start manufacturing:

March	April	May	June	July
				

BARDA H7N9 Preparation Budget

Countermeasure	FY17(\$)	Request(\$)	Total(\$)
Vaccine antigen (40 M doses) ¶	3 M	72 M ¹	75 M
Adjuvant (12 M doses)	9 M	79 M ²	88 M
Syringes and supplies (21 M)	0	9 M ²	9 M
Total	12 M	160 M	172 M

1 FY20172 FY2018¶ Includes development of virus seeds



Presentation to HHS Secretary

NIAID's Clinical Development Plan for H7N9 Vaccine

Anthony S. Fauci, M.D.

Director

**National Institute of Allergy and
Infectious Diseases**

National Institutes of Health

April 3, 2017



NIAID H7N9 Influenza Proposed Vaccine Trials: Assumptions

Based on trials that were rapidly conducted by NIAID in response to the 2009 H1N1 influenza pandemic

- **Use of a licensed technology**
- **Preclinical and Phase 2 clinical data from 2013 H7N9 adjuvanted vaccine trials may be leveraged for the regulatory review of planned trials in 2017**
- **Two candidates under consideration**
- **Candidates require two doses of vaccine**
- **Each dose of vaccine requires an adjuvant**

NIAID H7N9 Influenza Proposed Vaccine Trials

- **Phase 2 trials (several hundred volunteers) evaluating safety and immune response**
 - Healthy Adults
 - Elderly
 - Children
 - Pregnant Women
 - Mix and Match (Vaccine from Company A + Adjuvant from Company B)
 - Concomitant with Seasonal (Adults)
 - Concomitant with Seasonal (Children)
- **Trials would be conducted via the NIAID Vaccine and Treatment Evaluation Units (VTEUs)**

NIAID H7N9 Influenza Proposed Vaccine Trials

■ Healthy Adults: \$13.6M

■ Elderly: \$19.6M

■ Children: \$21.5M

■ Pregnant Women: \$11.2M

■ Mix and Match: \$9.3M

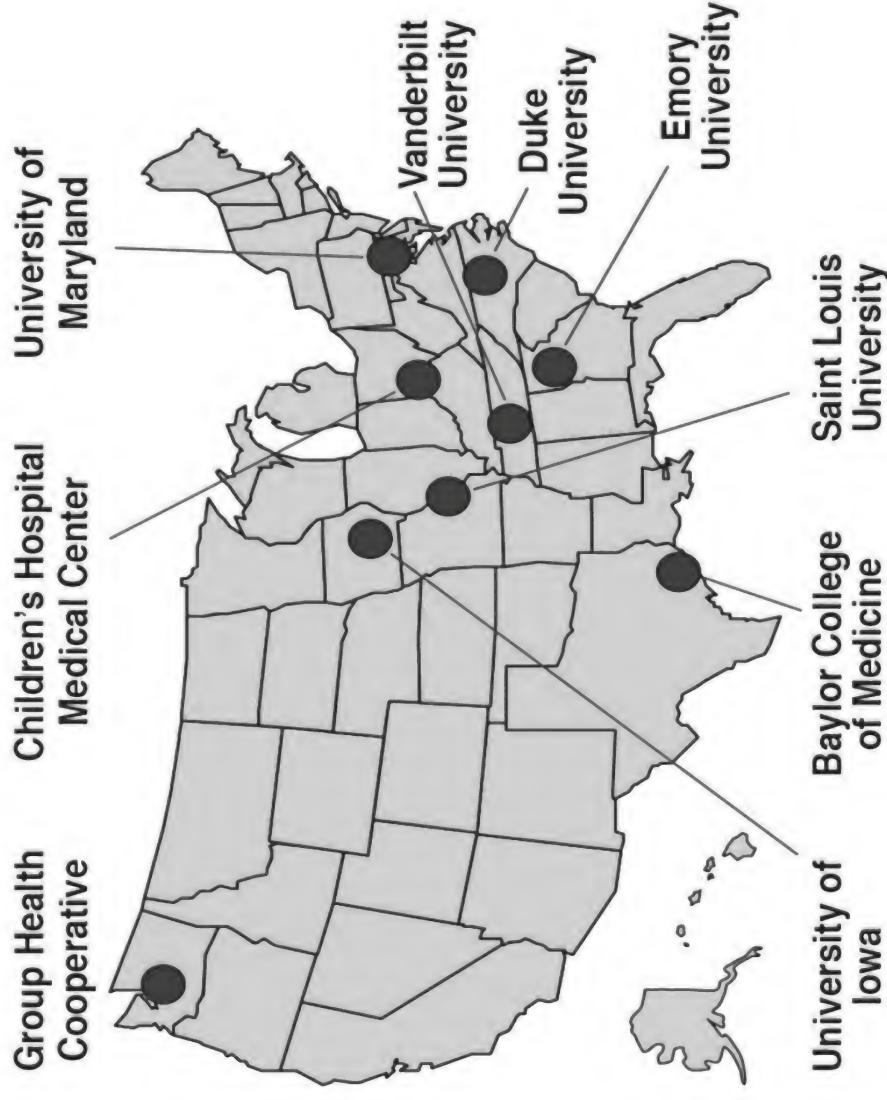
■ Concomitant with Seasonal (Adults): \$9.9M

■ Concomitant with Seasonal (Children): \$10.8M

**Total
cost:
\$96M**

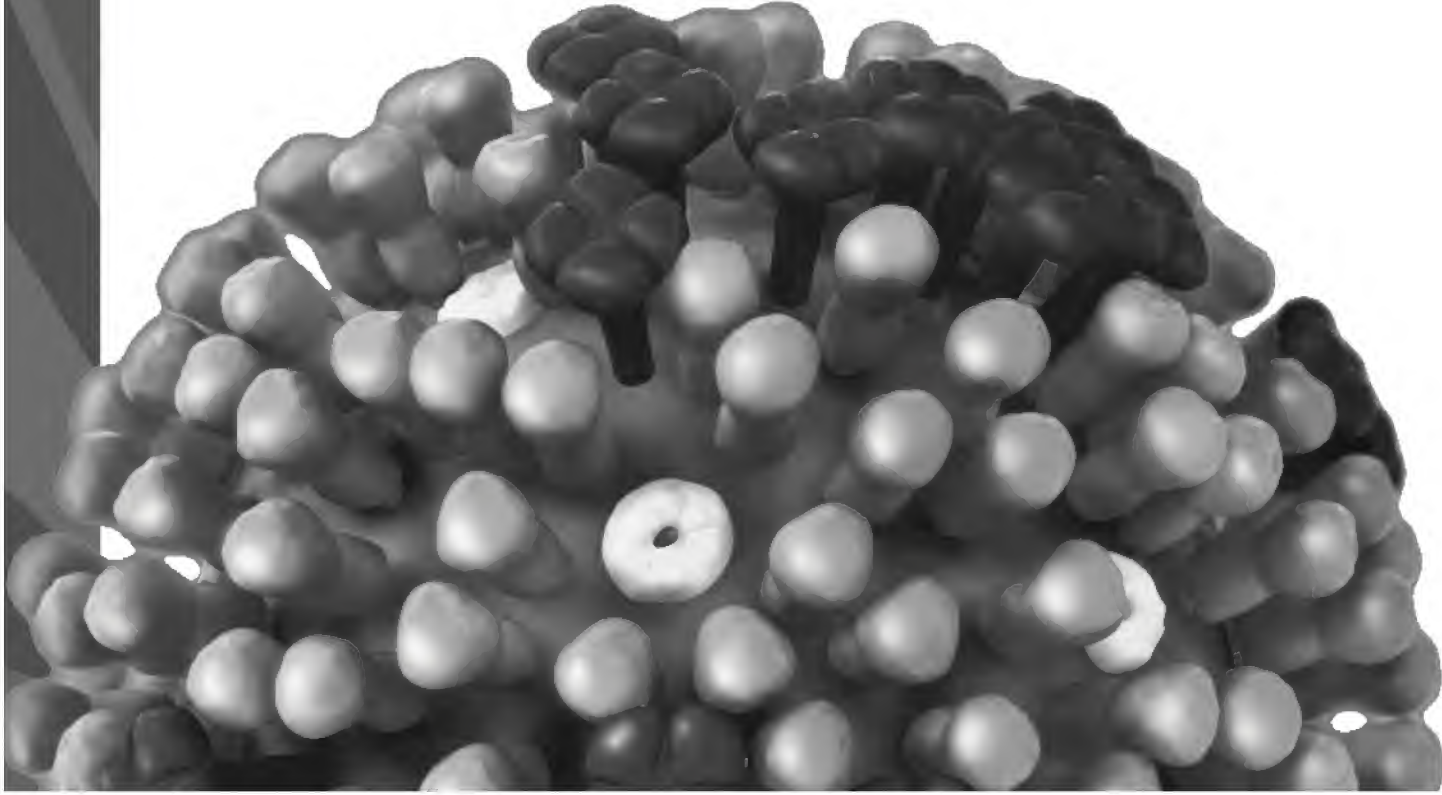
NIH's Network of Vaccine and Treatment Evaluation Units (VTEUs)

- Established in 1962
- Clinical trials for vaccines, therapeutics, and devices
- Access to diverse population types (e.g., pediatric, elderly, infected individuals)
- Expanded scope:
 - International trials
 - Epidemiologic and sample collection studies



Avian Influenza A(H7N9) Fifth Epidemic Wave Update

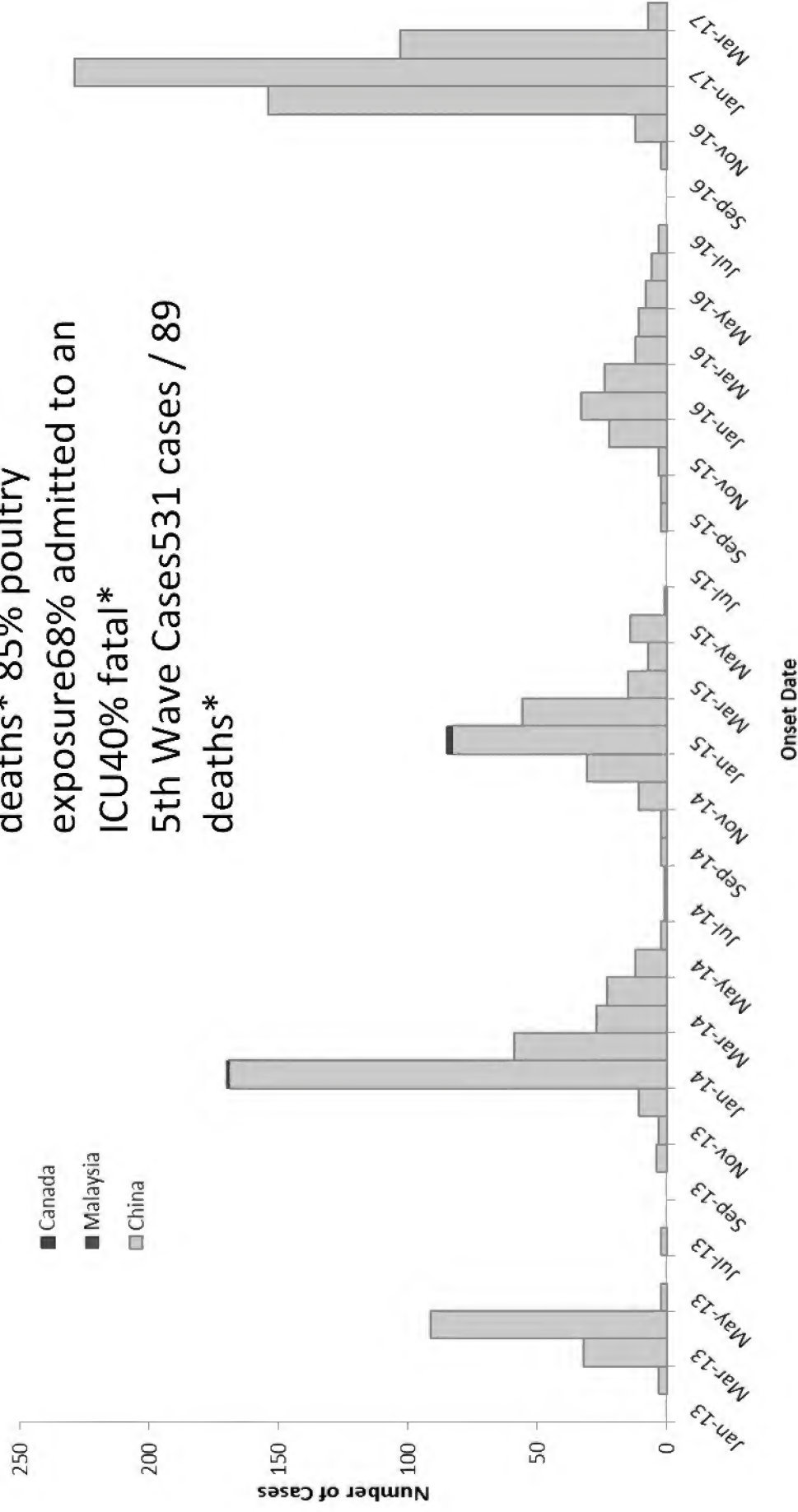
Anne Schuchat, MD (RADM,
USPHS) Acting Director
Centers for Disease Control and
Prevention April 3, 2017



Five Waves of H7N9 in China – Human Cases

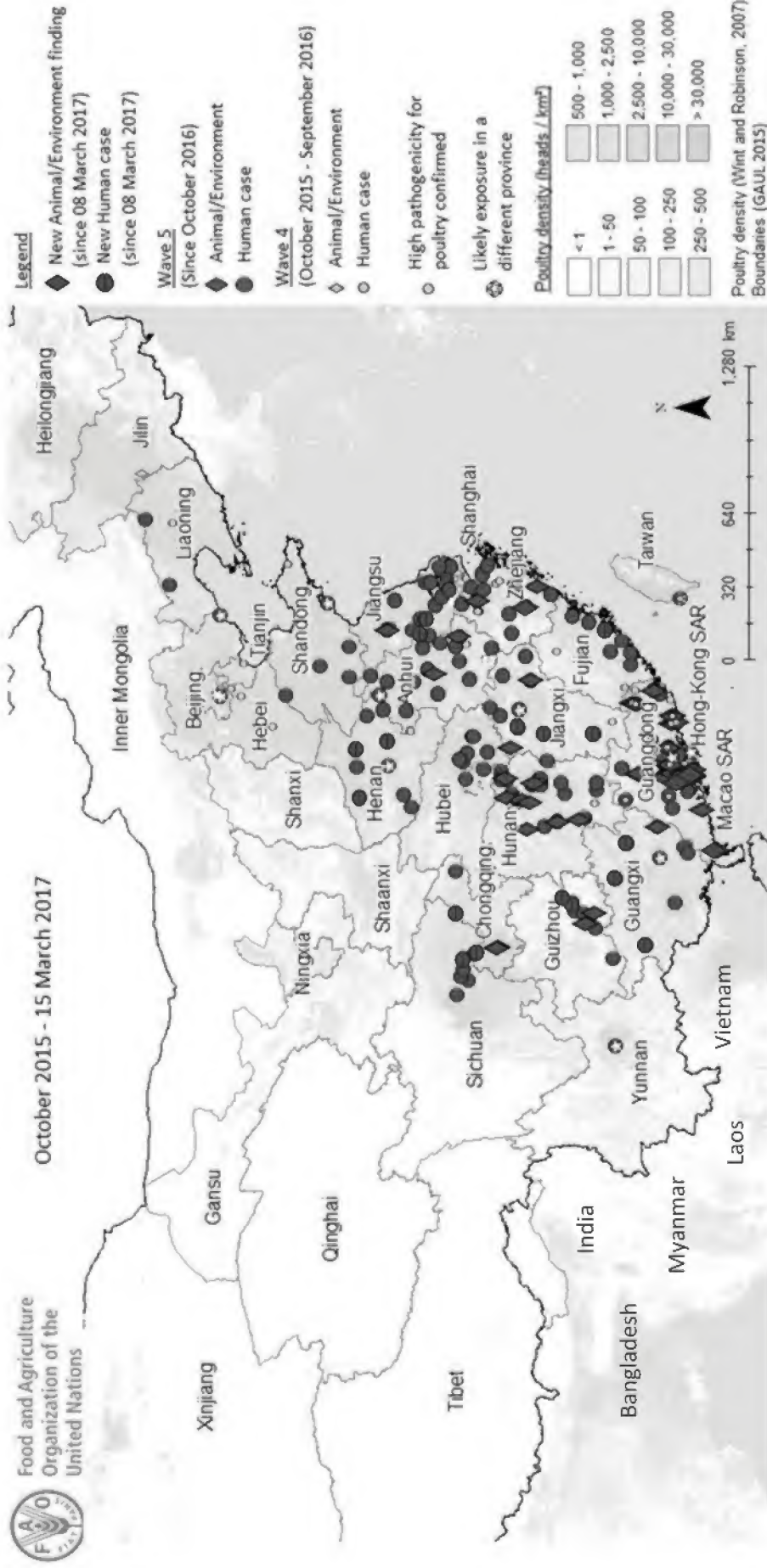


- Total Cases 1329 cases / 412 deaths* 85% poultry exposure 68% admitted to an ICU 40% fatal*
 5th Wave Cases 531 cases / 89 deaths*

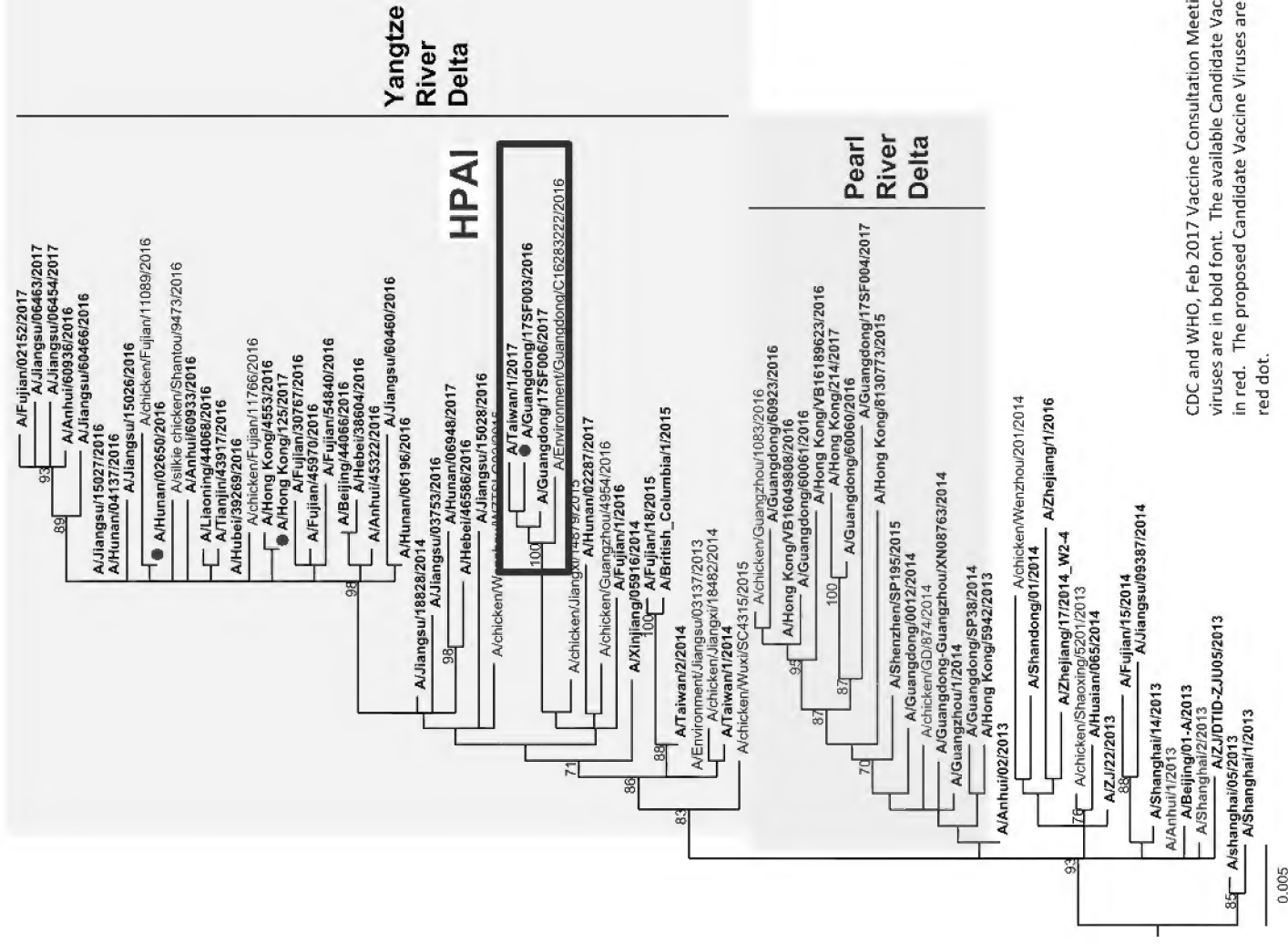


Avian Influenza A(H7N9) Human Cases. WHO.*An additional 93 deaths are still be reported. Case fatality of ~40% for waves 1 to 4 where final death reports are included.

H7N9 Affected Jurisdictions – 5th Wave



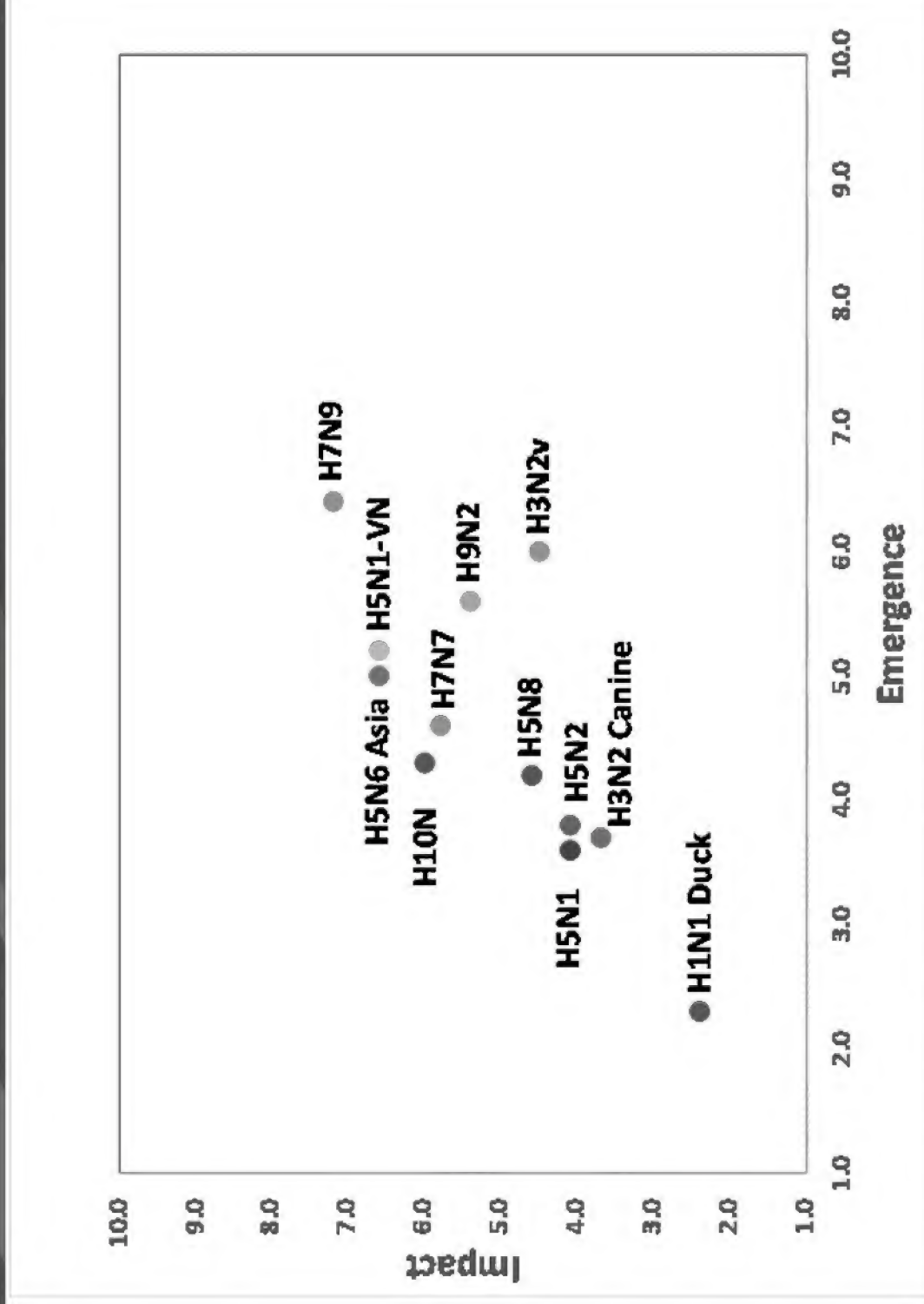
- Cases of infection are occurring in eastern, more populated provinces where poultry density is highest Vietnam MoH has placed their Emergency Operations Centers on alert and have increased surveillance



75 Viruses with Gene Sequences from 5th Wave 70 from “Yangtze” lineage New emerging lineage Does Not match stockpiled vaccine 5 from “Pearl” lineage Related to prior wave viruses Does match stockpiled vaccine Highly Pathogenic Avian Influenza (HPAI) Detected Emerged in Guangdong At least four human cases Causes poultry die-offs

CDC and WHO, Feb 2017 Vaccine Consultation Meeting. Human viruses are in bold font. The available Candidate Vaccine Viruses are in red. The proposed Candidate Vaccine Viruses are indicated by a red dot.

Influenza Risk Assessment – H7N9 Highest



- Scores reflect: 1) likelihood of emergence as a pandemic virus, and 2) likelihood that the virus will have an impact by causing severe disease. H7N9 in China has maintained the highest score since 2014.

- Vaccine Evaluated cross-protection of 2013 vaccine
Developing new Candidate Vaccine Viruses (CVVs)
Risk Assessment
Additional animal and lab tests underway
Rescoring IRAT with new information
International 15 CDC field staff in key locations & EIS officers available for deployment
Sending CDC diagnostic reagents globally
Providing support to 49 countries for global flu surveillance and response
Domestic Strategic National Stockpile (SNS) 60M antivirals
19K ventilators
Ongoing surveillance at 78 public health and DoD labs for seasonal and novel influenza
Around 75K specimens tested a year
Reagents identify novel influenza, H5 and H7

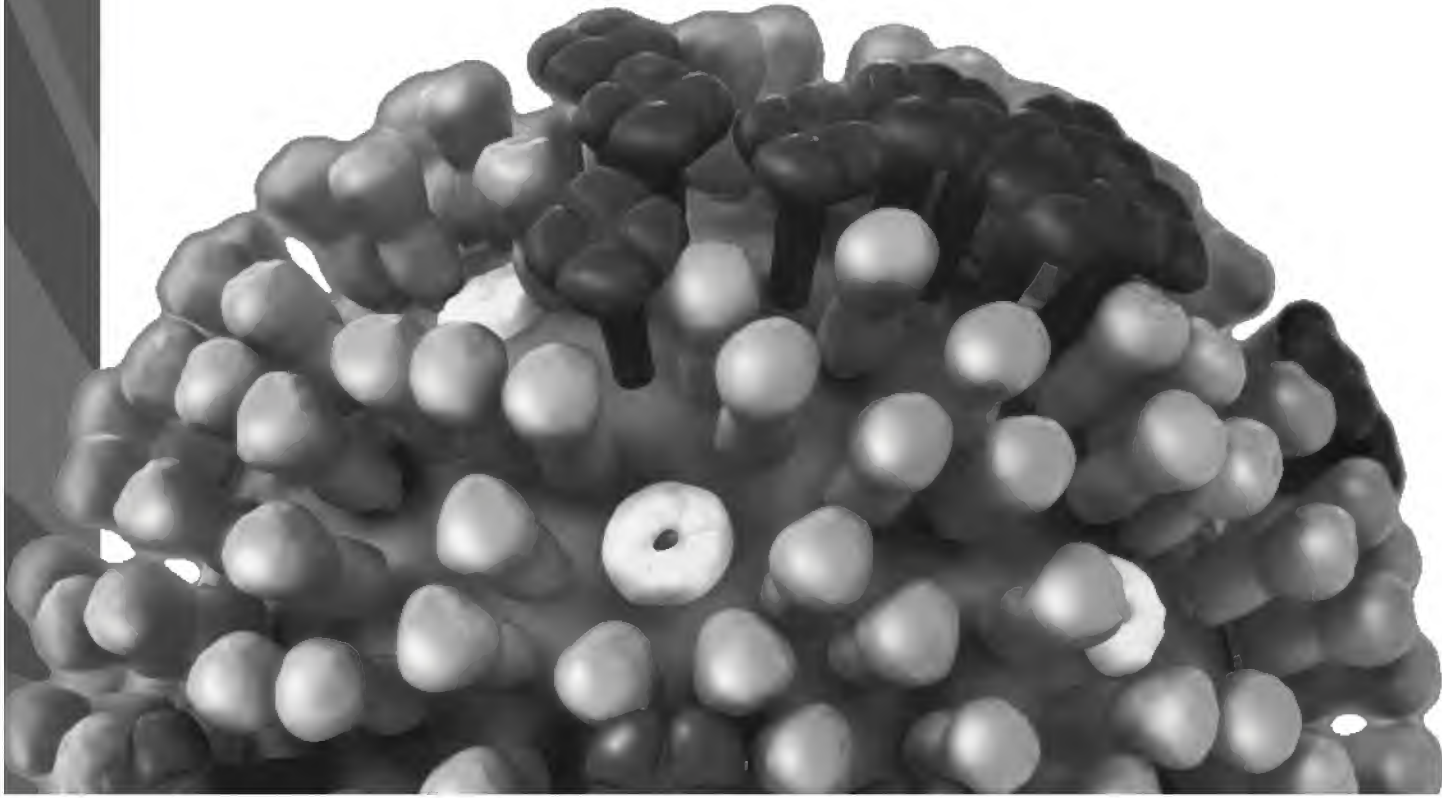
- Risk Assessment Influenza Risk Assessment remains highest of evaluated novel viruses No sustained and efficient Human-to-Human transmission Cases Increasing Human case numbers significantly higher this wave New highly pathogenic cases in province bordering Vietnam Virus Changing Genetic changes indicate need for new CVVs LPAI H7N9 maintains genetic markers associated with transmission to humans New Impact from HPAI Emergence of HPAI H7N9 likely to impact poultry business and MoAg response HPAI H7N9 infections in humans may have even higher severity similar to HPAI H5

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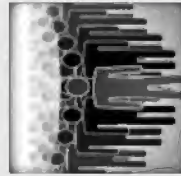

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of the Freedom of Information Act

Extra Slides



- CDC Influenza Risk Assessment Tool (IRAT) Ten elements of the virus, population immunity, and animal/human ecology are evaluated to develop a score

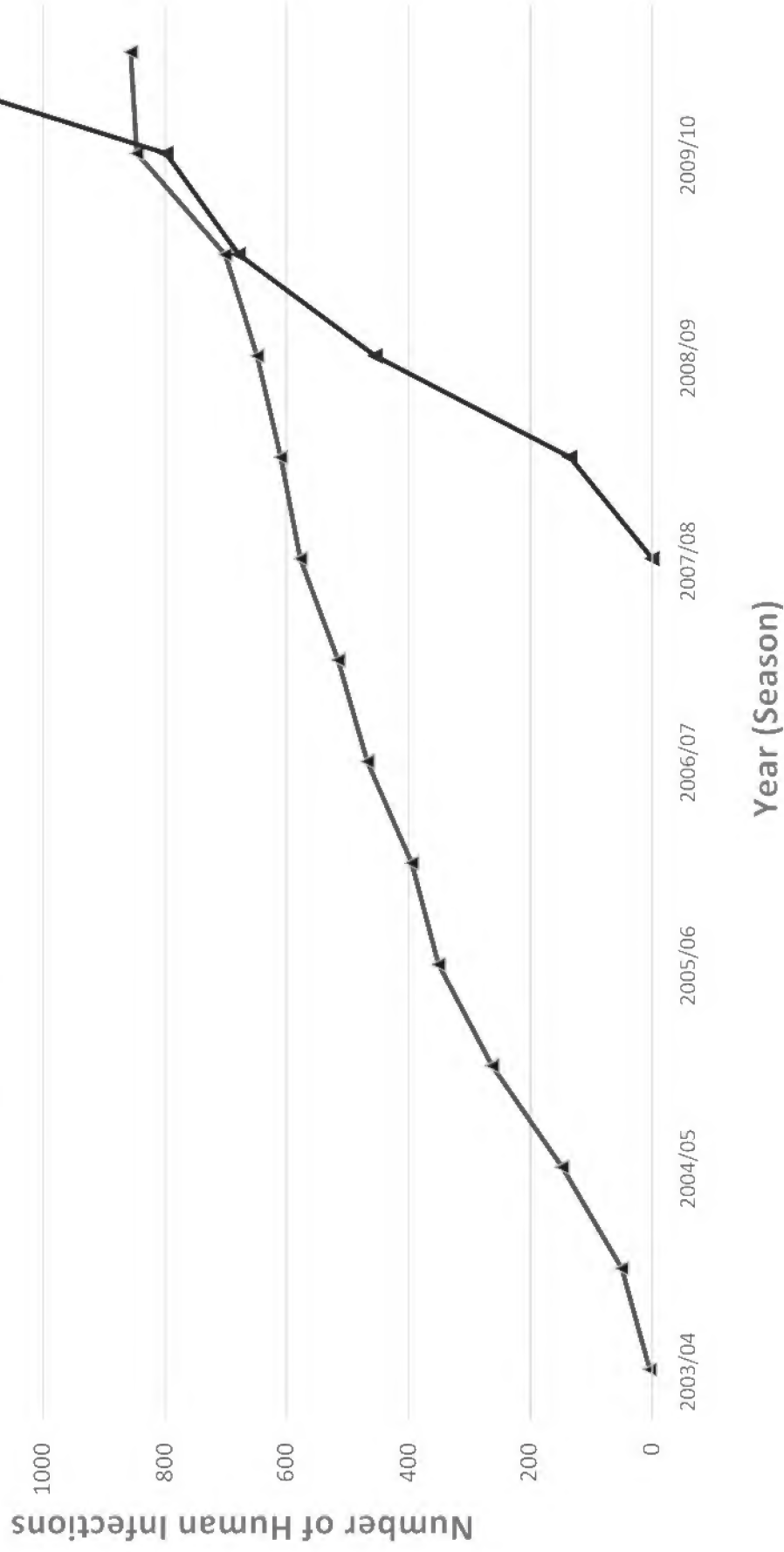
<div data-bbox="548 1619 748 1822">  </div> <div data-bbox="781 1665 828 1791"> <p>Virus</p> </div>	<div data-bbox="516 321 1073 1491"> <p>1. Genomic variation Receptor binding Transmission in Laboratory animals Antivirals and Treatment Options Existing Population Immunity Disease Severity and Pathogenesis Antigenic Relationship to Vaccine Candidates Global Geographic Distribution Infection in Animals, Human Risk of Infection Human Infections and Transmission</p> </div> <div data-bbox="878 1627 1057 1801">  </div> <div data-bbox="1073 1587 1122 1837"> <p>Population</p> </div>	<div data-bbox="1162 1619 1317 1822">  </div> <div data-bbox="1341 1623 1393 1816"> <p>Ecology</p> </div>
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H7N9 Overtakes H5N1 Numbers in Five Years



Cumulative Number of Human Infections of Avian Influenza
A(H5N1) and A(H7N9) by Year

—▲— A(H5N1) —▲— A(H7N9)





DATE: March 31, 2017

TO: Thomas E. Price, M.D., Secretary

THROUGH: Paula M. Stannard, Senior White House Advisor for HHS
Ann C. Agnew, Executive Secretary

FROM: George W. Korch, Jr., Ph.D., Acting Assistant Secretary for Preparedness and Response

SUBJECT: April 3, 2017 Briefing on H7N9 and Request for Vaccine Funding Decision

OVERVIEW

Avian influenza viruses—with their potential to infect, spread rapidly, and cause significant morbidity and mortality to humans—represent one of the greatest threats to global public health and security. Over this winter, there has been a surge in human cases of avian H7N9 influenza A virus infections in China. This has caused concern among U.S. and international experts and triggered technical and policy discussions on appropriate actions for pandemic preparedness.

In 2013, the influenza A (H7N9) virus first emerged as a new avian virus with human pandemic potential in poultry markets in China. During that year, the U.S. Department of Health and Human Services (HHS) experts and leadership determined a need to produce and stockpile a vaccine for this new virus, consistent with national and HHS policy.

Since 2013, the virus has continued to emerge in poultry and lead to cases of human infection in China among people in close contact with poultry for each of the past four winter seasons. Characterization of H7N9 viruses at the Centers for Disease Control and Prevention (CDC) and in China have now identified genetic and related antigenic evolution within these H7N9 viruses, such that the currently stockpiled H7N9 vaccine will no longer provide adequate protection to humans infected by currently circulating viruses from this group. It has been determined that a new vaccine needs to be developed, tested in clinical trials, and stockpiled to prepare for potential further spread of this new H7N9 influenza virus.

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of the Freedom of Information Act

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of the Freedom of Information Act

**Appendix 4: Briefing Slides that the Presenters will Use during the Meeting:
CDC, NIH, ASPR/BARDA**

Appendix 5: Briefing Timeline and Participants

Title: Secretary's Briefing on H7N9 Avian Influenza Virus

Date: April 3, 2017

Time: 11:30am – Noon

Location: Secretary's Large Conference Room (610F)

Purpose: ASPR will facilitate a briefing about the H7N9 avian influenza virus currently circulating in parts of the world. Divisions of the Department will discuss required resources to combat the spread of the virus and develop a vaccine. The Secretary is being asked to approve use of the remaining pandemic influenza supplemental funds for the proposed H7N9 preparedness activities.

Participants: **Secretary:** Thomas E. Price
Chief of Staff: Lance Leggitt
Counselors: Paula Stannard, Mary-Sumpter Lapinski
Exec Sec: Anne Agnew, Wilma Robinson, Ekaterini (Kat) Malliou
ASPR: George Korch, Edward Gabriel, Rick Bright
ASFR: Jen Moughalian, Norris Cochran
OGA: Mitchell Wolfe, Thomas Alexander, Kyle Zebley, Kamran Daravi
NIH: Anthony Fauci
CDC: Anne Schuchat
FDA: Lu Borio
OGC: Jeff Davis, Heather Flick
ASL: Barbara Clark, Laura Kemper

Presentation Timeline: **11:30am – 11:35am** – Introduction – George Korch (ASPR), Mitchell Wolfe (OGA)
11:35am – 11:40am – Epidemiology – Anne Schuchat (CDC)
11:40am – 11:45am – Vaccine – Rick Bright (ASPR/BARDA)
11:45am – 11:50am – Clinical Trials – Anthony Fauci (NIH)
11:50am – 11:55am – Funding – Norris Cochran (ASFR)
11:55am – 12:00noon – Questions and Answers

Material: Paper and Slides, attached.

Contact: If you have additional questions, please contact Ekaterini (Kat) Malliou in Exec Sec at Ekaterini.Malliou@hhs.gov, (202) 690-6875. Cell: (b)(6)

From: Lapinski, Mary-Sumpter (HHS/IOS)
Sent: 4 Aug 2017 13:55:05 +0000
To: Stannard, Paula (HHS/IOS)
Subject: HHS/SBA List Meeting

Meeting Participants:

HHS:

Mary-Sumpter Lapinski, Counselor to the Secretary, Public Health and Science
Laura Pence, Policy Advisor

Susan B. Anthony List:

Billy Valentine, VP for Public Policy
Autumn Christensen, Policy Director
Chuck Donovan, President, Charlotte Lozier Institute
Dr. David Prentice, VP and Research Director, Charlotte Lozier Institute
Dr. James Studnicki, VP of Data Analytics, Charlotte Lozier Institute
Dr. Donna Harrison, Executive Director, American Association of Pro-life OBGYNs

Topic: HHS/SBA List Meeting

Location: HHS, 200 Independence Ave, SW, WDC, Conf Rm 611E

POC: Geraldine Adair, 202-260-6149; Geraldine.Adair@hhs.gov